UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	) MDL NO. 2804
	) HON. DAN A. POLSTER
THIS DOCUMENT RELATES TO ALL CASES	) Case No. 1:17-md-2804

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SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

The videotaped 30(b)(6) deposition of H.D. SMITH by and through GEORGE EUSON, called for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before JULIANA F. ZAJICEK, a Registered Professional Reporter and a Certified Shorthand Reporter, at the offices of Brown, Hay & Stephens, LLP, Suite 800, 205 South Fifth Street, Springfield, Illinois, on November 27, 2018, at 9:13 a.m.

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REPORTED BY: JULIANA F. ZAJICEK, C.S.R. NO. 84-2604.

I N D E X

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PREVIOUSLY MARKED EXHIBITS

PREVIOUSLY MARKED EXHIBITS (Continued)

EXHIBIT		FIRST TIME REFERRED TO
HDS-EUSON-055	E-mail dated September 7, 2017, from Teva to H.D. Smith requesting information from 3 of H.D. Smith's customers - unable to release Oxy; HDS_Euson_00313 - 317	313
HDS-EUSON-057	Profit Sharing of Fentanyl between Actavis and H.D. Smith; HDS_Euson_00668 - 673	321
HDS-EUSON-058	E-mail dated April 19, 2006 to George Euson from Diversion Investigator Lynda Eleazer re: Budget Drug & Wellness Center's Suspended DEA Numbers; HDS_Euson_00674 - 675	323
HDS-EUSON-060	US Court of Appeals Opinion re: Masters vs. DEA, Decided June 30, 2017; HDS_Euson_00685 - 722	325

THE VIDEOGRAPHER: We are now on the record. My name is Anthony Micheletto. I am a videographer for Golkow Litigation Services.

Today's date is November 27th, 2018. The time is 9:13 a.m. as indicated on the video screen.

This video deposition is being held in Springfield, Illinois in the matter of In Re National Prescription Opiate Litigation, MDL 2804, in the United States District Court for the Northern District of Ohio, Eastern Division.

Will counsel please identify themselves for the video record.

MR. YOUNG: James Young on behalf of the Plaintiffs.

MS. COOK: Renee Cook on behalf of the Plaintiffs.

MR. MARTINEZ: Juan Martinez on behalf of the Plaintiffs.

MR. McBRIDE: Andrew McBride on behalf of Cardinal.

MR. YINGLING: Patrick Yingling for AmerisourceBergen.

MR. LEEDER: Bill Leeder on behalf of H.D. Smith.

MR. PADGETT: Bill Padgett on behalf of H.D. Smith and George Euson to the extent it wades into individual questions.

THE COURT REPORTER: If there is anyone on the phone, would you please introduce yourselves.

MR. MILLER: Well, yeah, Hayden Miller from Ropes & Gray on behalf of Mallinckrodt and SpecGx.

MS. LANGSTON: Nicole Langston from Jones Day on behalf of Walmart.

MR. MANNIX: Paul Mannix on behalf of HBC Services.

MS. MONAGHAN: Meghan Monaghan from Covington on behalf of McKesson.

MS. CAMPBELL: Kristen Campbell for Prescription Supply, Inc.

THE VIDEOGRAPHER: Our witness today is George Euson. Our court reporter is Juliana Zajicek. Please swear in the witness.

(WHEREUPON, the witness was duly sworn.)

GEORGE EUSON,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. YOUNG:

Q. Good morning, Mr. Euson. My name is James Young and I am here on behalf of the Plaintiffs in the national opioid litigation, as the videographer just relayed.

Can you state and spell your last name for the record?

A. Yes. It is Euson, E-u-s-o-n.

Q. And you're appearing here today as the corporate designee for H.D. Smith LLC, is that correct?

A. Correct.

Q. And you're familiar with Rule 30(b)(6)?

A. I am.

Q. You've appeared as a corporate designee under Rule 30(b)(6) for H.D. Smith in previous litigation?

A. I have.

Q. How many occasions did you testify as the 30(b)(6) witness for H.D. Smith previously?

A. Twice, I believe.

Q. I'm going to just go through a few basic rules just to -- I -- I know you've been deposed several times. I just want to make sure that you're

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up to snuff on -- on how this will go. We'll try not to speak over each other. I know from reading your prior transcripts that's not really an issue with you.

You want to give your counsel and any other counsel appearing here today a chance to make an objection, though unless they specifically instruct you not to answer, you should proceed with answering the question that's asked.

This is videotaped, as you can see by the cameras around. You are certainly welcome to make any facial gestures and nod or shrug your shoulders, but we'd ask that you always give a verbal response to every question. There may come times when I ask a question that doesn't make sense, that my wife reminds me about all of the time. I'll try to rephrase it in a way that makes sense for you, just let me know you don't understand the question and I'm certainly try to rephrase it in a way that -- that helps you get to an answer.

If you don't know the answer to a question, let me know that as well and we'll try to identify through your testimony the correct person who is in a position to answer that for H.D. Smith.

And -- and finally, if -- if you need a

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break at any time, you know, bathroom break or water or collect your thoughts or you want to talk to counsel, just let us know and we'll try to facilitate that as quickly as possible.

Tomorrow we are scheduled to take your deposition on an individual basis as a fact witness. So today I'd ask you to frame your answers on behalf of H.D. Smith. In essence, you are H.D. Smith today.

There may come times in these questions where we are going to seek testimony of George Euson the individual to color some of the background of your answers, so I know that's -- that can be a bit confusing. I'm going to try my best to make it clear that we are seeking H.D. Smith testimony today and tomorrow will be George Euson testimony.

Any questions before we dig in?

A. No.

Q. Okay. You have seen, I assume, the Amended First and Amended Second 30(B)(6) Notices of Deposition before today?

A. I have.

Q. And you're prepared today to answer questions, I think all of the questions -- or -- or subjects that were framed in the Amended First Notice

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of Deposition, is that correct?

MR. PADGETT: A through N?

MR. YOUNG: Yes, A through N.

BY THE WITNESS:

A. Yes.

BY MR. YOUNG:

Q. And in the Amended Second Notice you are prepared or your -- your -- your counsel has agreed to answer certain of those questions in writing, and you're here today to answer a subset of those questions. And I have those designated as 5, 6, 7, 10, 11, 12, 15 through 21.

Is that your recollection as well?

MR. PADGETT: He'd -- he'd have to see them.

THE WITNESS: Yeah.

BY MR. YOUNG:

Q. And that was -- that was going to be the next step is I'm going to -- I'm going to hand you a copy of the Amended Second Notice of Deposition, if you can just take a look at that. And see if that refreshes your recollection about what you are prepared to --

THE WITNESS: What's the topic?

MR. PADGETT: 5, 6, 7, 10, 11, 12.

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THE WITNESS: Is that 15?

On this? These here?

MR. PADGETT: Um-hum.

BY THE WITNESS:

A. Okay.

BY MR. YOUNG:

Q. Okay. And I'm going to hand you also just a copy of the Amended -- you can keep that one.

A. Okay.

Q. This is the Amended First Notice. This is the A through N that you are prepared to testify on.

And we had premarked -- we are going to go through a number of documents today. We have premarked them and numbered them as exhibits that go in seq -- sequential order and we overlooked these two documents in that numbering, so we've asked the court reporter to number and attach these as an exhibit to this deposition calling these Exhibits A and B, but all other exhibits are going to be referred to in numerical sequence from 1 through 60.

So just -- just so you know, when I refer to an exhibit, and I'll -- I'll either hand you a document or -- or refer to one that's in front of you, it will be Euson Exhibit 001, I'll just call it

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Exhibit 1.
A. Okay.
Q. Okay. So, before we jump into the documents, I just want to touch briefly on your background, just to understand a little bit how you got to H.D. Smith and what puts you in the position to answer as the corporate designee under Rule 30(b)(6).
Did you happen to bring a copy of your CV or resume with you today?
A. I did not.
Q. Is that something -- and -- and -- and maybe this is better asked of counsel.
MR. YOUNG: Is that something that has been previously introduced in -- in discovery? Do we have a copy of his --
MR. PADGETT: I don't think it's been requested.
MR. LEEDER: Yeah, I don't think it's been requested, but the answer is no, we haven't produced it.
BY MR. YOUNG:
Q. Okay.
So it's my understanding that you actually have a few different time periods where you were with H.D. Smith and then you left and went and did

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something else.
Could you just ex -- explain for us how you came to H.D. Smith and when you left, which periods of time?
A. I came to H.D. Smith in -- in November of 2005. Prior to that I worked about four years as director of security and compliance for a company called D&K Healthcare in St. Louis. And in '05 they were purchased by McKesson Corporation.
I then went to work for H.D. Smith as director of security and compliance. I was there from November 2005 to end of May 2008. And then I went into a private business, family business, until April 2009. I came back to H.D. Smith.
Just to clarify, during that time that I was gone, I was under a consulting contract with H.D. Smith. So I left but I was still involved with H.D. Smith.
I worked at H.D. Smith from April of 2009 until October of 2013. I then left for another business within the industry called Pro Compliance. I worked there for about a year and then I started my own consulting company in the pharmaceutical area.
Also during that time when I was -- when I

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was gone from H.D. Smith I was under a consulting contract also. And then I went back to H.D. Smith in May of 2016 to present.
Q. And you are currently employed by H.D. Smith LLC?
A. I am.
Q. And what is the title that you hold at H.D. Smith?
A. Vice president of corporate compliance and security.
Q. Is that the title that you held prior to your most recent departure?
A. The first time and second time I was director of -- of corporate compliance and security.
Q. Did your job duties change with this new title?
A. Not necessarily.
Q. It was just a promotion?
A. Promotion, yeah.
Q. What are your current duties for H.D. Smith as the vice president of compliance?
A. I oversee all -- all compliance as far as related to due diligence, our order monitoring program. I also oversee our licensing, which is all

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of our facility licensing, accreditation, such as VAWD accreditations throughout all of our facilities.
One of the people that work for me also is in charge of recalls. We do ARCOS reporting for the company. And then we also complete all of the -- if we get subpoenas or requests for information in from either industry or government, I have people that work for me that -- that put that information together.
And then we also do -- we are also in charge of internal compliance at our facilities. So we -- we are in charge of doing audits of our facilities to make sure that they are in compliance either with DEA, OSHA, FDA requirements, such as that.
So pretty much anything -- and -- and then physical security of all of our facilities.
Q. Is it fair to say that you are the most senior person at H.D. Smith with compliance responsibilities?
A. Yes.
Q. Who do you report to?
A. Right now I report to David May at AmerisourceBergen. He is the vice president of diversion control. Previously I had reported to Tom Twitty who was the senior vice president at

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H.D. Smith.
Q. Is Tom Twitty still with H.D. Smith?
A. Yes.
Q. Is he in a compliance capacity?
A. Not necessarily. He is mostly operations, limited regulatory, compliance responsibilities. I just reported to him.
Q. Okay. And, but you would -- you're -- you're of the belief that you have more background information about compliance as it pertains to H.D. Smith than Tom Twitty?
A. Yes.
Q. Okay. You mentioned Pro Compliance.
Is Pro Compliance a -- a contractor or a vendor for H.D. Smith?
A. It is.
Q. And at some point you went and worked for Pro Compliance.
Did you ever consider that to be a potential conflict --
A. No.
Q. -- between Pro Compliance and H.D. Smith?
MR. PADGETT: Object to form.
He answered.

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BY MR. YOUNG:
Q. I'm sorry. Was it?
A. No, it was not.
Q. Was the acquisition of H.D. Smith by Amerisource, do you -- and I -- I think you mentioned that you now report to an Amerisource employee.
Do you know whether or not you are going to maintain your position as vice president of compliance at H.D. Smith?
Has anyone mentioned that -- that to you?
A. Not right now. The -- I'm retained until August 2nd of 2019 in that capacity.
Q. And -- and what will happen after August 2nd?
A. I don't know.
Q. Okay. Okay. Fair enough.
So H.D. Smith is in the business of distributing pharmaceutical products. Is that fair and accurate?
A. Pharmaceutical products, OTC, health and beauty, pretty much anything you would find in a pharmacy.
Q. Is H.D. Smith LLC in any other type of businesses beyond the distribution of pharmaceuticals

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and OTC and the other products you just mentioned?
A. No.
Q. And --
A. We -- caveat that. I mean, there -- we've -- there are some ancillary businesses. I think they did a little bit of packaging. There was a specialty division that they had, a third-party network that was part of the company that no longer is.
Q. So the current iteration of H.D. Smith LLC is only in the distribution business?
A. Yes, sir.
Q. Okay. What type of pharmaceutical products does H.D. Smith distribute, just -- just generally? I know that there is a vast array of products that are out there. If you could just briefly describe.
A. Pretty much most of the brand or generic pharmaceutical products that are in the market, including controlled substances and non-controlled substances.
Q. Is there --
A. Full line wholesaler, full line.
Q. Sorry.

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A. I'm sorry. I didn't mean to walk over you.
Q. I think I did it to you. Apologies.
Is there any type of regulation over these products, government regulation?
A. Which products are you talking about?
Q. Pharmaceutical products.
A. Yes.
Q. What type of regulations exist for these products?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Can you be a little bit more specific, because there is a lot of them?
BY MR. YOUNG:
Q. Sure.
So, let's begin with schedules of pharmaceutical products.
Does H.D. Smith distribute any Schedule II pharmaceutical products?
A. Yes.
Q. Are there particular regulations that apply to Schedule II pharmaceutical products?
A. There is a lot of different regulations as

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far as storage, security, you know, from -- from receiving to -- to distribution.
Q. And -- and which are the entities that regulate Schedule II pharmaceutical products?
A. DEA and FDA.
Q. Are there any state entities that specifically regulate Schedule IIs?
A. There are state regulations that -- that touch on the requirements for -- for scheduled drugs. DEA is the main regula- -- regulatory agency that controls Schedule IIs.
Q. I'm going to show you a document that is -- been premarked as Euson Deposition Exhibit 1, 0001.
I'm going to give you a little bit of time.
A. Is there something you specifically wanted me to look at?
Q. I was going to give you some time to take a look at it.
A. Oh, okay.
Q. Are you familiar with the information contained in Exhibit 1?
A. Yes.

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Q. On Page 2 of Exhibit 1, there is a definition of controlled substances that has been pre-highlighted on the copy that you have.
Can you read that into the record for us?
A. "Schedule II/IIN Controlled Substances (2/2N): Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence. Examples of Schedule II narcotics include: hydromorphone (Dilaudid), methadone, meperidine, oxycodone (Percocet) and fentanyl. Other Schedule II narcotics include: morphine, opium, codeine and hydrocodone. Examples of IIN stimulants include" -- do you want me to read that or just that?
Q. That's fine. Thank you. Just the highlighted portion.
A. All right.
Q. Does H.D. Smith have any reason to disagree or dispute with the statements that are made on Exhibit 1 about controlled substances?
A. With regards to the highlighted areas?
Q. Yes.
A. No.
Q. So H.D. Smith agrees that controlled

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substances under Schedule II have a high potential for abuse which may lead to severe psychological or physical dependence?
A. Yes.
Q. Okay. I'm next going to show you a document that has been premarked as Exhibit 2, and it is actually a bit hard to --
MR. PADGETT: Do you want these back?
MR. YOUNG: You -- actually, yeah, I'll take them back. You already have a copy? Yes, I'll take them back.
BY MR. YOUNG:
Q. This next one is been premarked as Exhibit 2, and it is a bit longer than the last one, though, again, it has been pre-highlighted. I'm just going to give you a chance just to take a look at the highlighted portions.
I should mention, by the way, that the last exhibit that you looked at was actually from the DEA Diversion Control website, and this exhibit is also from the DEA Diversion Control website.
Just let me know when you're --
A. Okay.
Just that one page?

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Q. I believe so, yes.
Can you tell me -- the highlighted section, which this is from Title 21 USC Section 823 sub (b), sub (1) through (5), can you tell me whether or not that section, and we'll read it in a second, whether or not it applies to H.D. Smith?
A. It would.
Q. Is H.D. Smith a -- a registered distributor of Schedule II pharmaceutical products in the United States?
A. We are.
Q. Can you read for us the first paragraph of subsection (b) which is highlighted on Exhibit 2?
A. Subsection (b): Distributors of controlled substances in Schedule I or II. And it says:
"The Attorney General shall register an applicant to distribute a controlled substance in Schedule I or II unless he determines that the issuance of such a registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:
"(1) maintenance of effective controls against diversion of particular controlled substances

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into other than legitimate medical, scientific, and industrial channels;

"(2) compliance with applicable State and local law;

"(3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;

"(4) past experience in the distribution of controlled substances," excuse me, "and

"(5) such other factors as may be relevant to and consistent with the public health and safety."

Q. And, again, H.D. Smith has no reason to dispute or disagree that these are the requirements for distributors like H.D. Smith?

A. Yes.

Q. And we are going to dig into a little bit more throughout the documents and throughout your deposition today whether or not H.D. Smith maintained effective controls against diversion, it's a central tenet of this case, but I'm just curious preliminarily if you have an opinion on behalf of H.D. Smith whether or not H.D. Smith, in fact, maintained effective controls against diversion for Schedule II products

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throughout its tenure?

MR. PADGETT: I'll object to form. He can answer.

BY THE WITNESS:

A. Could you repeat that?

BY MR. YOUNG:

Q. Sure.

Is it your opinion here today or your -- your testimony today that H.D. Smith maintained effective controls against diversion of Schedule II controlled substances throughout its tenure as a pharmaceutical distributor?

MR. PADGETT: Same objection.

BY THE WITNESS:

A. We take our responsibility to maintain effective controls against diversion and we have done so.

BY MR. YOUNG:

Q. Has there ever been an instance in which H.D. Smith has failed to maintain effective controls against diversion?

A. Not to my knowledge.

Q. Has H.D. Smith ever failed to comply with applicable state or local law with regard to being a

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registered distributor of Schedule II controlled substances?

MR. PADGETT: Object to form, scope.

BY THE WITNESS:

A. Could you repeat that again?

BY MR. YOUNG:

Q. Sure.

Has H.D. Smith ever failed to comply with applicable state and local laws which apply to the distribution of Schedule II controlled substances? It is Section 2 of that section that I just read.

MR. PADGETT: Same objection.

BY THE WITNESS:

A. Could you be a little bit more specific to that?

BY MR. YOUNG:

Q. Is H.D. Smith aware of any prior instances where it failed to comply with state laws?

MR. PADGETT: Go ahead.

BY THE WITNESS:

A. I'm trying to think. You know, I don't know how specific you want to get on that, on state laws. I mean, there has been issues in some states where we have been cited for some violations.

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BY MR. YOUNG:

Q. So H.D. Smith has violated state laws before?

MR. PADGETT: Object to form.

He can answer.

BY THE WITNESS:

A. We have been cited for that.

BY MR. YOUNG:

Q. Is it your testimony today that you resolved those investigations or enforcement actions but did not actually violate the laws?

MR. PADGETT: Same objection.

BY THE WITNESS:

A. We received citations. We did not have any actions against our registration or -- any actions against our registration.

BY MR. YOUNG:

Q. Has H.D. Smith ever had its license suspended or revoked in any state?

A. It has not.

Q. Has the DEA or FDA or Department of Justice ever instituted an enforcement action or investigation against H.D. Smith?

A. Can you be more specific?

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Q. Are you aware of any instance in which the DEA has instituted an enforcement action or investigation against H.D. Smith?
MR. PADGETT: I'll object to form.
BY THE WITNESS:
A. DEA in -- instituted an investigation in our Kentucky facility, our Kentucky distribution center back in 2010 with an administrative inspection warrant.
BY MR. YOUNG:
Q. And --
A. -- and subpoena.
Q. And what was the result of that action?
A. No action taken.
Q. Is that the only instance in which the DEA has investigated H.D. Smith?
A. We've had cyclical routine inspections. And I don't know how -- what DEA considers those, if they are investigations. You know, to us they were cyclic inspections. There was a -- a lawsuit that we were involved with with -- with DEA, SafeScript case. I don't know if I'd consider that an investigation or not.
Q. How about the state enforcement

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authorities, whatever they may be called, in -- in some states I think it's the Board of Pharmacy, in other states I think it may be called something else.
Have any state regulators or enforcers instituted an investigation or litigation against H.D. Smith?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. We've had citations in California for -- for some violations of not getting a pharmacist signature on deliveries, such as that. Other than that, unless you can be more specific --
BY MR. YOUNG:
Q. Sure.
A. -- nothing is really coming to mind.
Q. How about the State of West Virginia, has the State of West Virginia Attorney General's office or Board of Pharmacy or any other regulatory entity instituted an investigation or enforcement action against H.D. Smith?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. We were involved in litigation with the State of West Virginia.

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BY MR. YOUNG:
Q. What was the basis of that litigation?
MR. PADGETT: I'll object to form.
BY THE WITNESS:
A. I'm not a -- I'm not ex -- exactly sure.
BY MR. YOUNG:
Q. Let's go at it a different way.
A. So if you can --
Q. Were you the chief compliance officer of H.D. Smith at the time that that West Virginia enforcement action was instituted?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I can't remember the exact dates that -- that that litigation covered and I was at H.D. Smith for part of it and some not.
BY MR. YOUNG:
Q. So what was your understanding in your compliance capacity as to why the State of West Virginia Attorney General was bringing an investigation or action against H.D. Smith?
MR. PADGETT: Object to form and scope.
BY MR. YOUNG:
Q. Do you not recall?

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A. I'm just -- I -- it has been a while for that. It was -- it was regarding controlled substances in the state with the -- concerning the opioid epidemic --
Q. Do you --
A. -- in the state.
Q. Do you know the allegations that the Attorney General made in its Complaint against H.D. Smith?
A. I believe one of them was a -- a failure to report suspicious orders to the state.
Q. And as the -- and I'm going to use the phrase "chief compliance officer." I understand at the time that you may not have held that title but that's essentially the role that you filled.
As the chief compliance officer for H.D. Smith, what, if anything, did you do when you learned of these allegations?
A. Well, as far as the allegation of failure to report suspicious orders to the state, it was our understanding that we were not required to as an out-of-state wholesale distributor. I know that, yeah, there was a lawsuit filed and went through the same -- same steps as we are doing through here.

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Q. By "here," you mean the litigation that we are here for?
A. This litigation, yes.
Q. Do you know the result of that litigation, the West Virginia litigation?
A. H.D. Smith paid a -- a fine. I'm not exactly sure how much it was.
Q. You're familiar with the Controlled Substances Act of 1971?
A. Yes.
Q. And is the Controlled Substances Act of 1971 something that H.D. Smith must comply with?
A. It is our responsibility to comply.
Q. Does H.D. Smith recognize that if you don't follow the rules in the Controlled Substances Act that you can be fined by the Federal Government?
A. Yes.
Q. And similar question with regard to the state Controlled Substances Act. Various states have enacted their own versions of a Controlled Substances Act.
Is H.D. Smith of the opinion that it must comply with the state Controlled Substances Acts in the states in which it operates?

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A. Yes.
Q. And failure to comply with those laws or rules would result in fines or license revocation.
Is that accurate?
A. I believe that that can be the -- the result.
Q. I'm going to show you another exhibit, which is Exhibit 3.
This exhibit is also from the DEA Diversion Control website and it has a very brief highlighted section at the top.
I'd just ask you to read the highlighted portion into the record and we can talk about it.
A. Okay.
Q. Can you read the highlighted portion into the record, please?
A. "All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances."
Q. Are you familiar with this language of this section?
A. I am.
Q. And has H.D. Smith complied with this requirement throughout its tenure as a pharmaceutical

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distributor?
A. Our responsibility is to provide effective controls against theft and diversion.
Q. That wasn't my question.
My question is: Has H.D. Smith complied with this throughout its tenure as a pharmaceutical distributor?
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. In other words, have there been occasions in which H.D. Smith has failed to provide effective controls and procedures to guard against theft and diversion of controlled substances?
MR. PADGETT: Same objection.
BY THE WITNESS:
A. To the best of my knowledge, we have complied with this regulation.
BY MR. YOUNG:
Q. The highlighted section uses the word "diversion."
What is your understanding of the term "diversion," what does that mean?
A. Diversion can -- basically it's illegal, when you are talking about controlled substances, it

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is an illegal -- acts or any -- anything pertaining to the controlled substances that would be illegal. It could be theft, it could be abuse.
Q. The section uses the -- the phrase "theft and diversion." So separating out theft from diversion, what's your understanding of diversion?
A. The controlled substances going into illicit channels, illegal use of controlled substances.
Q. You -- you used the phrase "illicit channels." Can you be more specific what you mean by that?
A. It could be channels in the supply chain that are -- you know, it could be counterfeit, it could be, you know, criminal type, you know, sale -- illicit sales, illegal sales of controlled substances, illegal use of controlled substances.
Q. Would diversion include obtaining prescriptions through forged prescriptions?
A. Yes.
Q. Would diversion include -- I think you -- you mentioned it, but just to clarify, would diversion include the resale of legally-obtained prescription controlled substances? So in other words --

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A. Obtained legally and then illegally sold?
Q. Yes.
A. On the street or what have you, yes.
Q. Have there been occasions in which H.D. Smith has uncovered, using your definition of diversion, the diversion of controlled substances in its tenure as a registrant under the Controlled Substances Act?
MR. PADGETT: Object; form.
BY THE WITNESS:
A. I can -- I can say that we may have suspected diversion. We don't do criminal investigations. We -- we may suspect diversion, we may report it. The end result may be down the line that there was illegal diversion, you know, a fact that someone, you know, was criminally prosecuted, but, you know, our responsibility is -- is -- is not to conduct criminal investigations. So I can't say for -- for a fact that, you know, what you asked.
BY MR. YOUNG:
Q. In your role as chief compliance officer, have you had occasion to investigate a pharmacy that you suspected was diverting controlled substances?
A. When you say "investigate," what --

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what -- can you define that a little bit more?
Q. Gather information or inquire.
A. We would gather information, we would conduct our due diligence, and then if we would have a reason to believe that there may be diversion taking place, then that would -- that would be reported, but we wouldn't necessarily go any further in -- into any kind of criminal investigation because that's not our -- our place.
Q. Okay. But there have been occasions in which H.D. Smith has concluded that diversion is likely at a pharmacy that it supplies?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. When we have reason to believe that there may be diversion taking place.
BY MR. YOUNG:
Q. Can you say -- and this is a difficult question, can you say approximately how many pharmacies that you identified as reason to believe that diversion was taking place?
A. We've probably -- I'll take a wild guess, 2- or 300 pharmacies, maybe more, that we have -- have reason to believe there may be diversion and we've

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either cut off entirely or at least cut off the -- the purchase of controls.
Q. And specifically with regard to what we will call CT-1 jurisdictions, which CT-1 jurisdictions include Cuyahoga County, the City of Cleveland, Summit County and the City of Akron, with regard to those four geographic communities, are you -- is H.D. Smith aware of suspected diversion taking place at pharmacies that it served as a distributor?
MR. PADGETT: Object to form to the extent suggesting we are a defendant in Summit County or Akron.
MR. YOUNG: Yeah, fair enough.
BY MR. YOUNG:
Q. So with regard to Cuyahoga and the City of Cleveland, has H.D. Smith ever identified pharmacies that it suspected were diverting controlled substances?
A. No.
Q. Have you undertaken investigations of pharmacies in Cuyahoga County or Cleveland and that you initially suspected were diverting controlled substances and concluded that they, in fact, were not diverting controlled substances?

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MR. PADGETT: Object to form.
BY THE WITNESS:
A. I'd probably like to get a little bit better idea of what you consider an investigation because -- or I can give you what our determinant -- or what we believe any -- any of our due diligence we consider part of an investigation.
In our due diligence we look at the totality of all circumstances. And we never suspected or had reason to believe that any pharmacies in Cuyahoga County or Cleveland were diverting.
BY MR. YOUNG:
Q. Fair enough.
I'm going to show you now what's been premarked as Plaintiff's Exhibit -- or Euson Deposition Exhibit 4. This is another printout from the DEA Office of Diversion Control. It has a highlighted portion.
I'm going to ask you to take a look at that and then read it into the record.
A. Do you want me to state the code or any -- and the part or anything?
Q. Ah, sure. That would be great.
A. Okay.

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Q. I failed to do so with the prior exhibit, so that's probably a good idea.
A. Title 21 Code of Federal Regulations, Part 1301, Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances. Security Requirements. This is 1301.74, subsection (b).
"The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."
Q. Are you familiar with the language in 1301.74(b)?
A. Yes.
Q. And what do you refer to or how -- how do you refer to this language, this requirement?
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. Within H.D. Smith, does it have a certain nomenclature or is this just a known --

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A. What time period are you talking about?
Q. Currently.
A. Currently, we have -- if this is what you are asking, we have an automate --
MR. PADGETT: Same objection.
Go ahead.
BY THE WITNESS:
A. We have an automated system called our Controlled Substance Order Monitoring Program, CSOMP for short.
Is that what you were referring to?
BY MR. YOUNG:
Q. Not -- not exactly.
A. Okay.
Q. This is -- this is part of the Controlled Substances Act requirements for registrants. And I was just curious if you had some nomenclature or would refer to this particular provision in a certain way? And specifically talking about the "suspicious orders include orders of unusual size, deviating substantially from a normal pattern, and orders of unusual frequency," that requirement.
You have no particular nomenclature you use in the industry?

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A. Not --
Q. Okay.
A. -- not particularly.
Q. In your opinion, did H.D. Smith comply with this requirement throughout your tenure with the company?
A. Yes, we did.
Q. Did H.D. Smith always have in place systems to identify suspicious orders as defined here in subsection (b) which you just read?
MR. PADGETT: Object to scope.
BY THE WITNESS:
A. We had a manual system and then we had an automated system. We had several iterations of that.
BY MR. YOUNG:
Q. And we'll dig into the details of those systems shortly, but is it your testimony today that at all times H.D. Smith complied with this requirement?
A. Yes.
Q. That includes during the manual system as well as the automated system?
A. Yes, sir.
Q. Who was responsible for ensuring that

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H.D. Smith complied with this provision, Section B?
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. Is that -- is that your job?
A. What time period?
Q. Throughout your tenure, if there is someone that was more senior than you and was responsible for compliance with this provision, I'd like to know them, but I'd also like to know whether or not this was your job?
A. When I first came to H.D. Smith in November of 2005 until -- when I first came there, it was the -- it was the responsibility of the individual distribution center managers, the operations managers to report suspicious orders to the field office in their area. That continued on until spring of 2008 when we got our -- our automated system running, and then that was brought in -- into the corporate office and under my responsibility.
Q. When you first got to H.D. Smith, was H.D. Smith in compliance with this provision?
A. I believe so.
Q. When you first got to H.D. Smith, was H.D. Smith reporting suspicious orders to the DEA when

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they were discovered?
A. At that --
MR. PADGETT: Object to form.
BY THE WITNESS:
A. At that -- at that time the -- the industry standard and the expectation from DEA was that orders were basically reported after the fact. They were -- if -- if we discovered an order beforehand, it would be reported before the sale.
Other than that, the operations managers reviewed orders at the end of each month and anything that they thought was unusual they would send that to the DEA. And that was the industry standard and the expectation at that time, which has changed over time.
BY MR. YOUNG:
Q. And -- and we'll get into that a little bit later, but with regard to the requirements as you read them in -- in Section B, is it your testimony that H.D. Smith was in or out of compliance with specifically reporting suspicious orders when they were discovered by the registrant?
So not with the DEA, I think your testimony was that the DEA allowed it to be done a certain way, but -- but I want to know with specific

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reference to this provision as it's written and as you read, was H.D. Smith in compliance?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Even if it was after the fact that our operations manager reported it, that was reported when discovered.
BY MR. YOUNG:
Q. Okay. So there were no delays between when an order was discovered and when it was reported to the DEA throughout the tenure of H.D. Smith as a registrant?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. What time period are you talking?
BY MR. YOUNG:
Q. Throughout H.D. Smith's history, are you aware of any instance in which H.D. Smith failed to report a suspicious order when it was discovered?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. No.
BY MR. YOUNG:
Q. Okay. You mentioned a transition from

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when you got there to H.D. Smith and the way that things were done and the changes that were made.
Did the senior management or board of directors of H.D. Smith have involvement or input over those changes?
A. Not necessarily.
Q. How were those changes implemented? In other words, you get there and you noticed things were being done in a certain way and you had recommendations to change them.
How is -- how are you able to implement those changes?
A. Shortly after I got there we had a meeting with DEA and I had consistent contact with DEA and headquarters. We -- any changes to the programs and -- and how we did things as we went along were -- there was never any interference from anyone, any management at H.D. Smith.
Q. So was there someone more senior than you that made it clear that whatever George recommends for compliance changes should be followed?
A. I -- I don't know that it was that rigid. They considered me as their compliance expert and they let me put in the -- the processes in place to -- that

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needed to be put in and improvements.
Q. H.D. Smith acknowledges that Section B of Part 1301 is a requirement that it's obligated to comply with, is that correct?
A. It's our responsibility to put -- comply with the law.
Q. And H.D. Smith acknowledges that as a registrant or distributor of controlled substances it must exercise due diligence to avoid filling suspicious orders, is that accurate?
A. Repeat that.
Q. Does H.D. Smith acknowledge that it must exercise due diligence to avoid filling suspicious orders?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. It is our responsibility, you know, within our -- our place in the supply chain to maintain effective controls against diversion and report suspicious orders when discovered as -- as to this regulation.
BY MR. YOUNG:
Q. And must H.D. Smith exercise due diligence in that regard?

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MR. PADGETT: Object to form.
BY THE WITNESS:
A. Can you clarify due diligence?
BY MR. YOUNG:
Q. Well, I'm -- I'm trying to understand what's the basis of H.D. Smith's compliance with these, with these laws, and you're the chief compliance officer. So I want to understand from H.D. Smith's perspective how should it comply with these laws? Should it do it willy-nilly or should it do it with due diligence?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. You know, part -- our -- our process and our procedures, you know, include due diligence to know our customers. You know, we put processes and procedures in place to get -- to understand the totality of circumstances and -- and the -- and to know our customers, their needs, if that is -- if that's what you are looking for.
BY MR. YOUNG:
Q. Yeah. No, that's -- that's fair.
A. Okay.
Q. In these three or four sections of

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regulations and laws that -- that we've discussed, Exhibits 1 through 4, what's the purpose of these, these laws?
Does H.D. Smith have an opinion as to the purpose of the Controlled Substances Act and the attendant regulations?
MR. PADGETT: I'll object to form.
BY THE WITNESS:
A. You know, our responsibility is to comply with the -- with the regulations.
BY MR. YOUNG:
Q. Well, why do these laws exist?
MR. PADGETT: Same objection.
BY THE WITNESS:
A. I wasn't there when they put the laws together.
BY MR. YOUNG:
Q. Does H.D. Smith have an opinion as to why these laws exist?
MR. PADGETT: Same objection.
BY THE WITNESS:
A. We comply with the regulations.
BY MR. YOUNG:
Q. Does H.D. Smith acknowledge that if it

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distributes controlled substances in this case, specifically opioids, that result in diversion, that the public could suffer harm?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Again, our -- our responsibility within the supply chain is -- is to maintain effective controls against diversion. Diversion comes in many forms and there is many forms of diversion that we have no control over.
BY MR. YOUNG:
Q. Does H.D. Smith acknowledge that if they distribute opioid orders deviating from a normal pattern and fails to report those to the DEA, that that would result in diversion?
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. In other words, let me rephrase that, that was an inartful question.
There are three types of suspicious orders that are defined or described in the section that you just read, Section B, and they are orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency, right? So

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we've got size, pattern and frequency.
When there is a suspicious order that deviates from a normal pattern, if H.D. Smith were to fail to report that suspicious order to the DEA, would that result in diversion?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I don't believe you can say a blanket statement like that.
BY MR. YOUNG:
Q. Is it possible?
MR. PADGETT: Same objection.
BY THE WITNESS:
A. Diversion is possible throughout the in -- throughout the supply chain.
BY MR. YOUNG:
Q. Is H.D. Smith aware of the great demand for opioid products through illicit channels like you described earlier?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Can you be a little bit more specific?
BY MR. YOUNG:
Q. Is H.D. Smith aware that there is a demand

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on the street for opioids?
A. Yeah, through our experience, yes, there is a -- there has been a demand for -- for opioids.
Q. Is H.D. Smith aware that the country is currently undergoing an addiction, an opioid addiction epidemic?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. You know, we stay -- stay abreast of -- of issues and I know CDC has called it an epidemic. I don't know the exact definition of an epidemic.
BY MR. YOUNG:
Q. Does H.D. Smith have an opinion on the current state of opioid addiction in the United States?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Can you rephrase that?
BY MR. YOUNG:
Q. Does H.D. Smith have an opinion on what's been described as the opioid epidemic? So I think you -- you didn't want to use the word "epidemic," so how would you define the current state of affairs with regard to opioid addiction in America?

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MR. PADGETT: Object to form.
BY THE WITNESS:
A. I didn't say I didn't want to use the word "epidemic." I said CDC has claimed it is an epidemic. And I don't know the exact definition of an epidemic.
I think that's subjective. But I do know that there is -- there are issues with opioids, there is issues with illicit fentanyl, there is issues with heroin, so yes.
BY MR. YOUNG:
Q. Does H.D. Smith acknowledge that opioids are addictive?
A. I believe they can be addictive.
Q. Does H.D. Smith acknowledge that opioids are dangerous in the wrong hands?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. You'd have to define dangerous and be a little bit more specific on that.
Q. Well, H.D. Smith --
A. And what the wrong hands are.
Q. H.D. Smith distributes opioids and we've agreed or you've admitted that opioids are addictive.
Is it your testimony that opioids which

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are addictive are not dangerous in the wrong hands or are dangerous in the wrong hands?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Again, clarify that, I -- I said that they can be addictive.
BY MR. YOUNG:
Q. Okay.
A. Okay.
And can you repeat your question again then?
Q. Sure.
These -- these drugs, these controlled substances, in this case opioids, if they were to reach the wrong hands, does their potential to be addictive, is that dangerous?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I'm not really clear on what you are asking. I mean --
BY MR. YOUNG:
Q. Okay.
A. -- what -- where -- you know, dangerous to the person, dangerous to society?

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Q. No, that's fair.
A. Yeah.
Q. As I mentioned at the outset, I may ask many a question that -- that doesn't make sense to you and I appreciate you letting me know.
Does H.D. Smith have an opinion as to whether or not pharmaceutical products, in this instance opioids, the type that it distributes, have caused harm in the State of Ohio?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I -- I can't say for certain that the drugs that we have distributed have caused harm to anyone.
BY MR. YOUNG:
Q. And I should have been more clear.
I don't mean specifically the drugs that you delivered but the types of drugs that you delivered, the controlled substance opioids have caused harm to the State of Ohio or in the State of Ohio?
MR. PADGETT: Object to form, scope.
BY THE WITNESS:
A. I'm still not exactly sure where you are

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going with that, but, I mean, opioids, you know, can be addictive, they can cause overdose deaths if -- if used incorrectly, if that's what you are getting at.
BY MR. YOUNG:
Q. Well, I -- I want to understand H.D. Smith, as a distributor of opioids, whether or not it has an opinion as to whether or not opioids have caused harm to, in this case, I'll even limit it further, the City of Cleveland and Cuyahoga County.
Have the City of Cleveland or Cuyahoga County residents and the government entities themselves suffered harm as a result of prescription opioids?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I'm still not clear exactly what harm you are asking about. You know, these -- you know, these drugs that -- that -- these opioid drugs that are distributed, you know, are -- that are used by -- by patients can be, you know, lifesaving, you know, drugs can -- can relieve people of pain, which they are intended to do, you know, for legitimate use and -- and legitimate patients.
BY MR. YOUNG:

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Q. Sure. And that wasn't my question. My question is the opposite of that.
It's have those same drugs caused harm. You've mentioned some of the benefits and I want to know about some of the harmful effects.
So does H.D. Smith have an opinion as to whether or not these prescription opioids that we are talking about generally, not the ones that it specifically distributed, but the type, whether or not that has caused harm in Cleveland and Cuyahoga County?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I don't know the specifics you are talking about, but can opioids be abused, can people die of overdoses, yes, if that's the harm you are talking about, my assumption is in Cuyahoga County people have died of -- of drug overdoses.
BY MR. YOUNG:
Q. And do you know whether or not Cleveland and Cuyahoga County drug overdoses have been the result of prescription opioids or I think you mentioned heroin and illicit fentanyl? Have you researched or have you come to a conclusion as to whether or not prescription opioids are part of that

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cause?
MR. PADGETT: Objection; scope.
BY THE WITNESS:
A. I don't know specifically.
BY MR. YOUNG:
Q. You haven't -- H.D. Smith hasn't done any research to determine whether or not Cleveland or Cuyahoga County has suffered harm as a result of prescription opioids?
MR. PADGETT: Objection; scope.
BY THE WITNESS:
A. I'm -- I'm still not sure what you mean by harm, but my assumption would be that there probably have been people that have died of overload -- of prescription drug overdoses in Cuyahoga County.
BY MR. YOUNG:
Q. Okay. I'm going to show you what's been marked as Exhibit 5, and this I'll give you in just a second, I'm sure that you are familiar with it, it has been pre highlighted, it is on DEA letterhead and it is dated September 27th, 2006.
Does that exhibit look familiar to you?
A. Yes, sir.
Q. This letter is from Joe Rannazzisi.

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Are you familiar with Mr. Rannazzisi?
A. Yes.
Q. Have you met him before?
A. I have.
Q. On how many occasions?
A. Maybe a couple.
Q. Did you receive this letter on behalf of H.D. Smith in approximately September of 2006?
A. This was sent to our distribution center, it would have been forwarded to me.
Q. So sometime thereafter you would have received it?
A. Yes.
Q. Do you recall receiving this letter specifically?
A. Not specifically.
Q. Can you read Paragraph 1 of that letter?
A. Not highlighted, the very first paragraph?
Q. Yeah.
A. Okay.
"This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this

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letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces."

Q. Mr. Rannazzisi references a prescription drug abuse problem the nation currently faces in September of 2006.

Did H.D. Smith have reason to disagree that a prescription drug abuse problem existed in 2006?

A. No.

Q. Do you know what Mr. Rannazzisi was referring to when he described the prescription drug abuse problem the nation currently faces?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. I am assuming that it is controlled substances since it's from -- since he is from DEA.

BY MR. YOUNG:

Q. So you were the compliance officer of H.D. Smith, a licensed drug distributor, you've received this letter in 2006, and your testimony today is you're not sure what the prescription drug abuse problem the nation faced was?

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MR. PADGETT: Object to form.

BY MR. YOUNG:

Q. You are un -- are you unclear?

A. I didn't say that. I said that the -- it is a prescription drug abuse problem. Prescription drug abuse can be anything. But I'm assuming it's -- what -- what he is referencing is controlled substance abuse.

Q. Yeah, fair enough. The -- and the letter does go on to -- to state that.

Can you turn to Page 2, there is a highlighted portion. And I want to circle back to some of your earlier testimony where you talked about the DEA and sort of their understanding of interpretations of the laws and whatnot. And we'll get to that in a second, but first, can you read for us the highlighted portions of Page 2?

A. "Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling sup" -- "suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels."

Q. Okay. So does H.D. Smith agree, disagree,

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or not have an opinion as to the accuracy of that statement?

MR. PADGETT: Object to form.

BY MR. YOUNG:

Q. That a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels?

MR. PADGETT: Same objections.

BY THE WITNESS:

A. We do exercise our due diligence.

BY MR. YOUNG:

Q. So H.D. Smith agrees that it has a statutory responsibility?

MR. PADGETT: Same objection.

BY THE WITNESS:

A. I'm not sure about the statutory responsibility, but we do, as a practice, exercise our due diligence.

BY MR. YOUNG:

Q. So what part of the statutory responsibility does H.D. Smith disagree with?

MR. PADGETT: Same objection.

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BY THE WITNESS:

A. I'm saying I'm not sure of a statutory responsibility, but we -- of -- to exercise due diligence, but we do, as a practice, exercise due diligence.

BY MR. YOUNG:

Q. So you disagree that there is a statutory responsibility to exercise due diligence when filling suspicious orders?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. I don't disagree. I'm saying that we do exercise our due diligence.

BY MR. YOUNG:

Q. That wasn't my question.

My question is whether or not you agree or disagree that there is a statutory responsibility to do so?

MR. PADGETT: Object to form, asked and answered.

BY MR. YOUNG:

Q. You can answer.

A. Oh, okay.

What I'm saying is I'm not clear about

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when they say a statutory responsibility for due diligence. We --
BY MR. YOUNG:
Q. So you are the chief compliance officer of H.D. Smith, I think your testimony has been that you are the senior-most person charged with compliance responsibility for H.D. Smith, and as we sit here today, you are not sure whether or not there is a statutory responsibility to exercise due diligence?
A. We exercise due diligence and our responsibility is to maintain effective controls against diversion, which we do, and we abide by the regulations.
Q. Okay. And I -- I guess we are in a bit of a echo chamber.
What I need to understand is whether or not H.D. Smith is of the opinion that there is a statutory responsibility to do those things? Because I'm still not getting a clear answer from you as to whether or not it is statutory in nature. So I'll ask it as clearly and cleanly as possible.
Is there a statutory responsibility, a legal obligation to exercise due diligence to avoid filling suspicious orders?

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MR. PADGETT: Object to form.
BY THE WITNESS:
A. I -- I don't -- I don't -- the statutory responsibility I'm not sure of. We do exercise due diligence. That's what we do as a practice, a process, a procedure when -- regarding suspicious orders.
BY MR. YOUNG:
Q. Why -- why do you do that? If there is not a statutory responsibility, why would you do that?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. As part of our effort to maintain controls against diversion.
BY MR. YOUNG:
Q. Which is based in law or you just decide to do that on your own?
A. No. It's our responsibility to comply with the -- with the law and the regulations.
Q. So there is law and regulations that require the exercise of due diligence?
MR. PADGETT: Same objection.
BY THE WITNESS:
A. What I'm telling you is I'm not sure what

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the statutory verbiage is regarding due diligence.
BY MR. YOUNG:
Q. Okay. That's fair enough.
The next paragraph that's highlighted there, can you read that for us?
A. "In a similar vein" -- "in a similar vein, given the requirement under Section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as Section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling."
Q. Is there anything in that section that H.D. Smith disagrees with?
A. No.
Q. There is another section in here -- where is -- can we come back to Page 1 of this document, and under Background, the second full paragraph, it begins with: "The CSA was designed."
A. "The CSA was designed" -- do you want me to read it?

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Q. Yes, can you read it, please. Sorry.
A. "The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components in the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."
Q. So, and I appreciate you reading that. It was lengthy, I know, and -- and there is a lot there, but what I want to know is whether or not there is anything in that paragraph that H.D. Smith disagrees with?

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MR. PADGETT: I'll object to form.
BY THE WITNESS:
A. I'm rereading it.
BY MR. YOUNG:
Q. Yeah, and if you want, we can do it -- we can do it sentence by sentence.
So the first sentence is --
A. Can I -- can I reread it first?
Q. Sure.
A. Thanks.
Okay.
Q. Okay. So, just after you read it a second time, is there any part of that that H.D. Smith disagrees with?
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. We can go sentence by sentence if you'd like?
A. It's not necessarily disagree, just, you know, some of the -- you know, when Congress envisioned, you know, I -- I don't know what was going through Congress's mind back then.
Q. Okay. Yeah, fair enough.
Do you have an understanding or belief as

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to what, other than described in this letter, what Congress may have envisioned distributors doing under the Controlled Substances Act?
In other words, do you have some disagreement with the conclusion here or are you just unaware?
A. I don't have any specific disagreement.
Q. The letter describes the distribution chain as a closed system.
Are you familiar with that phrase?
A. Yes.
Q. Can you explain to us what the closed system means?
A. Basically it's a -- closed system is from -- you know, DEA sets quotas for manufacturers of controlled substances on what they can manufacture. The manufacturer then, if -- if you go -- simplify the supply chain, sells product to distributors, all of that's recorded so that -- so that there is no diversion or theft inside that supply chain from manufacturer/distributor.
Same way, and you have to be registered with the DEA to handle controlled substances, the manufacturers are registered, the DEA distributor such

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as H.D. Smith are registered with the DEA.
Anyone then that we would sell to, whether it be a hospital, pharmacy, doctor, has to be a -- a registered -- registered with DEA also to handle controlled substances.
So we can only sell to DEA registrants, and that's all recorded. So it -- it keeps the system so that there is no introduction of other products, there is no -- if -- if -- you know, if there is theft, that would be discovered. And then on down to where we would sell to, again, a DEA registrant.
You've got a DE -- DEA registered practitioner that would be writing prescriptions filled at a DEA pharmacy -- or DEA registered pharmacy on until that it is dispensed to a patient, and all of that -- all -- all of that is tracked through the system in a -- what's considered a closed system.
Q. Perfect. Thank you.
I want to turn back to Page 2 of this document. It's -- Paragraph 2 says -- it -- it begins with "DEA recognizes," and -- and I'm just going to read it briefly to -- to get you acquainted with it. It's the third sentence.
"Nonetheless, given the extent of

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prescription drug abuse in the United States."
Can you -- can you read that for us?
A. "Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences" -- "consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."
Q. Does H.D. Smith agree or disagree with that statement?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Based on circumstances, it could.
BY MR. YOUNG:
Q. Is it your testimony that one distributor that uses its DEA registration to facilitate diversion can cause enorm- -- enormous harm?
A. Yes.
Q. The sentence also talks about the extent of prescription drug abuse in the United States. I know we've kind of talked about this a little bit, but does H.D. Smith have reason to dispute that at least in 2006 there was a prescription drug abuse problem in the United States?

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A. I don't dispute that.
Q. There is another section in here I want to draw your attention to, and, again, this is a letter that all distributors received from Joe Rannazzisi and you previously testified that you received this.
The third-to-last paragraph -- oh, no. You already read that. I'm sorry.
The -- the third-to-last paragraph which is highlighted on your sheet that you previously read, I think I've asked this, but does H.D. Smith acknowledge that there are additional responsibilities of distributors beyond just reporting suspicious orders?
A. You are referring to where it says: "Thus, in addition"?
Q. Yes.
A. Okay.
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. So, and -- and -- and I'll break it down, this section of the letter actually describes the reporting requirement as well as the duty to exercise due diligence to avoid filling the order.
Does H.D. Smith recognize and acknowledge

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that that is a requirement under the rules, regulations and laws which govern drug distribution?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. The regulation is -- as written is a regulatory responsibility to report suspicious orders.
BY MR. YOUNG:
Q. Okay. So does H.D. Smith disagree that there is also a responsibility to avoid filling suspicious orders?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. My understanding is that the regulation refers to reporting suspicious orders. We, as a practice, would not fill a suspicious order.
BY MR. YOUNG:
Q. So as the chief compliance officer of H.D. Smith, it is your testimony today that H.D. Smith could, if they so chose, fill a suspicious order?
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. And not violate the Controlled Substances Act?
MR. PADGETT: Same objection.

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BY THE WITNESS:
A. The regulation states that you must report suspicious orders. There is -- there is not a shipping regulation.
BY MR. YOUNG:
Q. Okay. So, and I don't want to testify for you, I just want to make sure that I get some clarity from you on this.
It is your testimony that there is no obligation of a drug distributor to halt a suspicious order?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. By regulation there is not. By practice and procedure and process, H.D. Smith does not ship any orders that we have identified as suspicious.
BY MR. YOUNG:
Q. Has it ever done so in the past?
A. Which time period?
Q. To your knowledge as a representative of H.D. Smith, has H.D. Smith ever shipped an order that it identified as suspicious?
A. Prior to our automated system when we were on a manual system, as was industry practice, there

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may have been orders that were reported after the fact that had already been shipped.
Q. And what happens to those orders? So once they are sent to a pharmacy and they are later identified as suspicious, what, if anything, does H.D. Smith do about that?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. At that time -- in that time period?
BY MR. YOUNG:
Q. At any time period.
MR. PADGETT: Object to form.
BY THE WITNESS:
A. It has changed throughout the years.
BY MR. YOUNG:
Q. So let's begin with your initial or first understanding of the way things were at H.D. Smith.
If H.D. Smith were to ship an order that was subsequently identified as suspicious, what is your first understanding of what they did with that order afterwards or -- or with that pharmacy/customer afterwards?
MR. PADGETT: Object to form.
BY THE WITNESS:

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A. You know, our responsibility was to report suspicious orders and by industry practice and -- and at the time and what was expected by DEA, we were complying with what -- what was expected and what was industry practice, which was report the suspicious order and it would have been after the fact at that time prior to the spring of 2008.
BY MR. YOUNG:
Q. Okay. And what I want to know is did H.D. Smith take any action, and they may not have, I don't know, did they take any action once they recognized that a suspicious order went out the door?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I'm not sure prior to me coming there.
BY MR. YOUNG:
Q. How about under your tenure?
A. We did investigate those when they were brought to my attention.
Q. Is there any ability to retract an order from a pharmacy that was shipped?
A. Not to my knowledge.
Q. Did you ever make an attempt to contact a pharmacy and explain that you mistakenly shipped an

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order in excess of what they were entitled to receive?
A. At that time, again, we need to talk about time periods, at that time there was no limit or whatever.
Q. Going back to this letter, this Rannazzisi letter from September of 2006, what, if anything, did you do with this letter? Did you distribute it, did you condense it to a memo, did you share it with anyone? What did you do with it?
A. Prior to this letter coming out, the -- again, I had had a -- this came out in September 2006. I had a meeting with DEA in January of 2006 that discussed much of the information that was in here. This letter is pretty much pertaining to internet-type pharmacies, the same way as the -- the meeting I had with DEA.
So we had already acted upon that. We had -- I had developed a presentation. I actually used much of the -- the presentation that DEA had provided me and provided that to our -- our distribution centers, our sales reps, our operations people to better inform them of what to look for regarding internet-type pharmacies.
Q. But specifically with regard to this

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letter, did you do anything with it or did you just read it and file it away?
A. We were already addressing the concerns that were in this -- when this letter came. So it's not like it just got filed away. We were already, you know, taking this to our people, to our salespeople at all of our divisions, to our operations people to inform them of things to look for, the things that are -- that are listed on -- on Page 3. We -- we started to put together a -- we started to explore an automated system that we could use to better adhere to our responsibilities.
Q. And we'll get into the automated system and whatnot, but I want to know, you know, practically speaking, when you received this letter, I know it was forwarded to you because it wasn't addressed to the -- to you at your -- at your office, after you received this specific letter, what you did with it? So not the information in it, but the letter itself, did you forward it to anyone?
A. I could have.
Q. You don't recall?
A. (Nodding head).
Q. Do you know whether or not senior

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management, so management at a -- at a status or hierarchy above yours received a copy of this letter?
A. These letters were -- were shipped to DEA registrants which would have been our -- our warehouses. Our corporate office is not a registered -- a registrant with DEA. They would not have received this. I can't tell you for sure. My assumption is I would have forwarded it to upper management. I can't tell you for sure.
Q. Do you recall any specific conversations that you had with senior management about the contents of this letter?
And I don't mean your prior meeting with DEA, you mentioned that January meeting, but specifically this letter?
A. No. I don't recall.
Q. Do you recall whether or not this letter was distilled or condensed in any form for sharing with other people in the compliance department?
MR. PADGETT: Object to -- object to form.
BY THE WITNESS:
A. I don't know what you mean by that question.
BY MR. YOUNG:

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Q. Were there other people in the compliance department at the time you received this letter?
A. I think one.
Q. Who was that?
A. P.J. VanDermeersch, P.J. Little at the time.
Q. Do you know whether P.J. received a copy of this letter either from you or from some other source?
A. I'm sure she did.
Q. Do you recall discussing the contents of this letter with P.J.?
A. I don't.
Q. Okay.
MR. YOUNG: Now is probably a good time to take a break. I think we've been going a little bit. I don't know if you need to use the restroom, but we'll go off the record.
THE VIDEOGRAPHER: We are off the record at 10:44 a.m.
(WHEREUPON, a recess was had from 10:44 to 10:55 a.m.)
THE VIDEOGRAPHER: We are back on the record at 10:55 a.m.

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BY MR. YOUNG:
Q. Mr. Euson, we -- we just took a break and I -- I know that you had a chance to communicate with your counsel. I don't want to know any of the content of what you may have discussed with them, but is there anything that you learned or were instructed that might change your testimony from the prior session that we just had?
A. No.
Q. So when we just left, we were looking at the Rannazzisi -- what I call Rannazzisi 1, the first letter. And I want to show you what I call Rannazzisi 2, which is another letter from Mr. Rannazzisi. This one is dated December 27th, 2007th -- 2007, and I'd just ask you to take a look at that.
Just like with regard to the first letter, I'll ask: Do you recall receiving a copy of this letter?
A. Yes.
Q. Is it your recollection that you received it around the time that it was dated in December of 2007?
A. I would assume.

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Q. The other thing I'd ask is: Do you recall what you did with this letter after you received it? Just like we discussed with the prior letter, did this letter receive the same treatment or different treatment as the prior Rannazzisi letter?
A. I don't recall exactly what I did with it.
Q. There is a highlighted portion of this letter. It begins in Paragraph 3, if I could ask you to read that into the record, please.
A. Do you want just the highlighted part?
Q. Yes.
A. "Filing a" -- "Filing a monthly report of completed transactions (such as, excessive purchase report or high unit purchases) does not meet the regulatory requirement to report suspicious orders."
Q. Okay. Does H.D. Smith agree or disagree with that statement?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. You know, this was part of the ever-changing guidance and interpretation by DEA and this was -- I do agree with it, and this was right at the time when we were putting together our automated suspicious order monitoring program, our Controlled

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Substance Order Monitoring Program, so...
BY MR. YOUNG:
Q. Did the laws or regulations change over time or the -- the changes that you are talking about are interpretations of the law?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. The laws them -- the laws themselves, the regulation?
BY MR. YOUNG:
Q. Yes.
A. The verbiage did not change. The interpretation and the -- of -- of how that regulation was complied with did change over time.
Q. And what did H.D. Smith rely upon to change the way it interpreted those laws? In other words, did you receive something in writing from the DEA which said: This is how you should conduct your program?
A. There was a series of events that happened and especially in 2007, we -- there was an industry conference in September that year in which a DEA representative gave a presentation on expectations of compliance with the regulation.

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At that meeting I was invited to come up to DEA headquarters in October of 2007 to discuss H.D. Smith developing an automated system and we met with DEA headquarters in October of that year and we began -- we -- we had started to develop an automated system but it wasn't -- we could never get it to work right.

We revamped it after that meeting and -- and after -- during that presentation and in September, DEA and a -- a person with A -- AmerisourceBergen put on a -- a joint discussion on order monitoring, and so we tried to fashion our order monitoring system to make it similar to AmerisourceBergen's and I had constant contact with DEA headquarters, Kyle Wright with the DEA, as we were developing it.

So I'm not sure exactly if this was your question, but this is where I'm going with it, so, you know, by -- from October to -- to April or March we were developing our system to -- to role out our automated system to better comply with the new interpretation or -- of -- of the regulation.

Q. And is it your position today that H.D. Smith was not obligated to comply with the letter

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of the law prior to the rollout of the automated system because of direction -- directives from the DEA?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. Our obligation was to comply with the regulation, and based on industry standard and the interpretation and with working with DEA at the time before our automated system, we believed we were complying with the regulation of reporting orders when discovered.

BY MR. YOUNG:

Q. So the -- prior to the implementation of your automated system, and that's under the manual system that -- that you described earlier, the manual system did not meet the requirements that are enunciated in the Rannazzisi '07 letter, did they?

A. We reported suspicious --

MR. PADGETT: Object to form.

Go ahead.

BY THE WITNESS:

A. We reported orders that we -- that our operations managers deemed as potentially suspicious to DEA after the fact, after they had been shipped, as

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was industry standard, and we were in compliance with what we believed was DEA's expectation of complying with that regulation.

BY MR. YOUNG:

Q. Okay. But that was not technically in compliance with the law as it was written, is that true?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. We believe we were in compliance with the regulation.

BY MR. YOUNG:

Q. And what was the basis for that belief? Did the DEA send you a letter blessing or sanctioning your program?

A. DEA will not do that.

Q. Did you rely upon the advice of outside counsel to lead you to conclude that your system was in compliance with the law?

MR. PADGETT: Ob- -- object to form.

I'll instruct you not to answer any attorney/client communications.

MR. YOUNG: On the development of CSOMP?

MR. PADGETT: Excuse me?

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MR. YOUNG: On the development of the suspicious order monitoring system?

MR. PADGETT: That wasn't your question.

BY MR. YOUNG:

Q. Did your system -- the automated system that you developed, were you under the impression that the automated system, which we'll talk about shortly, that that was in compliance with the letter of the law of the Controlled Substances Act?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. Regarding the section on -- on reporting suspicious orders?

BY MR. YOUNG:

Q. On any and every section of the Controlled Substances Act, was your automated system in compliance with that?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. We believed it was.

BY MR. YOUNG:

Q. Now, you -- you seemed to hesitate that you believed that it was. Is it -- is it 100 percent that it was in compliance or are you unclear as to

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whether or not it was in compliance?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I'm not unclear. My -- we believed that we were in compliance. We developed that automated system to somewhat mirror AmerisourceBergen's system that -- DEA won't bless or -- or say that any system -- there is -- there is no definition of a system that is authorized or -- or blessed by DEA. You know, I knew that DEA was involved with the development of AmerisourceBergen's. And then when we met with DEA at headquarters in October of 2007, I was in constant communication with DEA headquarters, Kyle Wright specifically at DEA headquarters, letting him know all along the way how we were developing that system. Would he give a blessing on it and say that's -- that's exactly what they want? No, they won't do that. So our belief, my belief is that we were in compliance with the regulation.
BY MR. YOUNG:
Q. Did anyone give you an opinion, a regulatory opinion, a -- a government opinion about whether or not your system was in compliance with the CSA entirely?

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A. No, but we also -- numerous cyclical inspections by DEA at all of our distribution centers and there was never anything brought up that our system was out of compliance.
Q. There is another highlighted section in this letter. It's a -- just a part of a sentence I'd just like you to read. It says -- it begins with: "Registrants must conduct."
Can you read that into the record?
A. Just the highlighted part --
Q. No, the whole sentence.
A. -- out of context?
Q. That sentence.
A. Pardon me?
Q. That sentence: "Registrants must conduct."
A. "Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels."
Q. Okay. So do you agree or disagree that that is a requirement under the Controlled Substances Act?
MR. PADGETT: Object to form.

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BY THE WITNESS:
A. The requirement is to report suspicious orders and the requirement is for us to maintain effective controls against diversion.
BY MR. YOUNG:
Q. Okay. That's not my question.
My question is: This sentence that is in the Rannazzisi letter to all registrants, does H.D. Smith agree that this is a requirement or does it disagree that that's a requirement?
MR. PADGETT: Same objection.
BY MR. YOUNG:
Q. And I would focus your attention on the temporal aspect, the "prior to completing a sale" provision.
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I -- I think that -- can you reword that question, because I --
BY MR. YOUNG:
Q. Sure.
A. This -- you know, there is also, you know, analysis of suspicious orders prior to completion of sales. You -- I need a little bit more context and a

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little bit more definition of exactly what you are looking for.
Q. So, as the chief compliance officer of H.D. Smith, as the corporate designee of H.D. Smith, what I would like to know is whether or not H.D. Smith views that sentence as a regulatory requirement that it is currently and historically complying with or not? If it dis -- if you disagree with it, that's fine, but I want to know whether or not you have been and are in compliance with that requirement, conducting an independent analysis of suspicious orders prior to completing a sale?
A. You --
MR. PADGETT: Object to -- object to -- object to form and scope.
BY THE WITNESS:
A. This -- this letter is not law and it is not regulation. We comply with the regulation regarding reporting suspicious orders and we comply with the regulation of maintaining effective controls against diversion.
BY MR. YOUNG:
Q. And -- and -- and I appreciate your testimony that this letter is not the law. I just

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want to know whether or not you disagree with the statement.

Do you disagree that registrants must conduct an independent analysis of suspicious orders prior to completing a sale?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. I -- I don't know what else to tell you, we -- we comply with the law as written and we consider these guidance documents.

BY MR. YOUNG:

Q. Okay. So is this a guidance document that H.D. Smith relies upon in interpreting and executing its responsibilities under the Controlled Substances Act?

A. We do analyze orders and if we discover a suspicious order we report it and we also do independent investigation on those orders.

Q. Okay. So H.D. Smith then conducts an independent analysis of suspicious orders prior to completing sales?

A. What time period?

Q. Let's start in 2008. Did it -- did it do that in 2008?

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A. Once we had our automated system up, yes, it was prior to the sale.

Q. Okay. So prior to the implementation of the automated system, it did not do this, H.D. Smith did not do an independent analysis of suspicious orders prior to completing sales.

Is that your testimony?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. With our -- with our manual system, there were times when orders were discovered prior to sale that were considered suspicious and reported and there were times it was after the sale at the end of the month when our operations managers went through prior sales and reported them as potential suspicious orders, but they were shipped out, it was after the fact.

BY MR. YOUNG:

Q. So this letter, the part which you initially read, filing a monthly report of completed transactions does not meet the regulatory requirement to report suspicious orders, is that a -- an accurate depiction of what H.D. Smith did prior to implementation of its automated system, the filing a

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monthly report of completed transactions, or was it something different?

A. Yeah, we are -- our operations managers at the time prior to our automated system would go through monthly reports at the end of the month and if they deemed that there was a pos -- a potential suspicious order, they would report that to DEA. It was after the fact. And then this letter was a guidance letter saying that we are not doing that anymore, now we are doing it before the sale.

Q. And -- and that's real -- really what I wanted to know is whether or not this letter was the initial indication to H.D. Smith that what it was doing was not sufficient.

Is this the first instance when H.D. Smith learned of that?

A. I wouldn't class -- I wouldn't say that it was insufficient. That was the industry standard and that was the expectation at the time. When I had the discussion with DEA, with our industry -- the industry meeting in September 2007, it was brought to people's attention at that conference, which is for distributors.

My individual meeting with DEA in October

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of 2007, they also brought it up before this letter, and that's when we started working diligently on our automated system so that we could comply with the new interpretation and expectation of DEA.

Q. Okay. So what was the first instance -- I think you mentioned three different points in time there.

What was the first instance in which H.D. Smith became aware that filing monthly reports after the fact does not meet the regulatory requirements?

MR. PADGETT: Object to the form.

BY MR. YOUNG:

Q. It might have been a phone call, it may have been an e-mail, it may have been a letter.

A. It was sometime at the end of 2007.

Q. Do you recall what it was, was it a letter?

A. I -- I don't specifically recall. It was -- you know, we talked about it at our meeting that we had in October and that's when we were going to develop our system. That's not something you can develop overnight, and DEA was well aware of that and knew that it would be springtime before we were able

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to get our automated system up and running to comply with the expectations, their expectations and the expectations of this letter, because that was not the industry standard and the expectation up to this point.

Q. The Rannazzisi letter also references on Page 2, I believe -- I think it is Page 2, yes. On the last paragraph it mentions a case. And it says:

"I refer you to the recent final order issued by the Deputy Administrator, DEA, in the matter of Southwood Pharmaceuticals," and it gives a -- a case citation.

Did you ever review the final order issued by the DEA in the Southwood Pharmaceuticals case?

A. Yes.

Q. What did you conclude after reviewing that final order?

A. It has been a while since I read Southwood, but my recollection is that it had to do mainly with they were supplying internet pharmacies with a lot of hydrocodone, if I recall correctly, and they were not reporting those orders to DEA, and consistently sold them even after they had been warned by DEA. That's my general recollection of it, so...

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Q. Did -- did you only review the Southwood Pharmaceuticals final order because of this Rannazzisi letter or were you otherwise aware of it?

A. I don't know exactly when I was aware of this. I think this final ruling, it looks like it was in 2007, so I don't know when that came out.

Q. Did you do anything with the Southwood Pharmaceuticals final order that you reviewed, did you share it with anyone at H.D. Smith?

A. I don't know if I exactly -- I -- I don't recall if I shared the actual ruling, but it was -- it was discussed at -- in compliance meetings and such that we would have had with -- with the divisions. We did annual compliance trainings with our sales reps and our divisions. And I know it was part of -- part of a PowerPoint that I would have had that -- that -- and I would have explained the gist of the Southwood ruling, that they had their registration revoked due to internet sales.

Q. Did they -- did H.D. Smith senior management express any concerns to you about being in violation of the CSA after learning about the Southwood Pharmaceuticals final order?

A. No.

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Q. Did you have concerns about being in violation of the CSA after reading the Southwood case?

A. Not that I believe, no.

Q. Was H.D. Smith of the belief that once it implemented its automated system that it would be in compliance with the DEA's expectations and interpretations of the CSA?

A. Yes.

Q. So prior to implementation of that, for the time period between when you first learned that you were not sufficiently complying with the letter of the law until you implemented the automated system, for that period of time isn't it true that you were in violation of the CSA?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. I don't believe so.

BY MR. YOUNG:

Q. Why not?

A. The DEA knew what we were doing, we had done some beta testing, we were trying to look at orders, we were reporting some when discovered, even though they may have been after the fact, but, you know, until we had our automated system up and

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running, you know, and we -- we did not have the ability to do that as far as the prior to sale.

Q. So am I to understand that H.D. Smith's inability to comply with the law somehow made it okay?

A. That's not what I'm saying.

Q. Okay.

A. I'm saying that we --

MR. PADGETT: I'll object to form.

Go ahead.

BY THE WITNESS:

A. We believed that we were in compliance with the law and the expectation from DEA in the way we were operating and we were never told anything differently. We had numerous dealings with DEA, we had numerous inspections by DEA, and nothing was brought up that we were in violation of -- of the -- of this regulation.

There were many pharmacies that we had reported that we do our due diligence where we can stop selling controlled substances to them and still nothing was ever mentioned that we were in violation of the regulation. And we did not believe that we were.

BY MR. YOUNG:

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Q. I'm going to show you what's been marked as Euson Deposition Exhibit 7. This is a DEA report of investigation of July 13th, 2006. It is of a Paragould Pharmacy, Semo Drugs of Kennett, SafeScript Pharmacy and Max Care Pharmacy.

Does that report look familiar to you? Have you seen that before?

A. I have never seen it.

Q. Is this the type of report that you would receive a copy of?

A. It looks like an internal DEA report. We would not -- I have never seen this, nor have I seen a report similar to this.

Q. This -- this report references -- where is this name -- you have never seen this exhibit before.

So have you ever seen this type of report before?

A. I have not.

Q. Do you know who Scott Garriott is?

A. Yes.

Q. How do you know Scott Garriott?

A. He is a diversion investigator that -- out of the Springfield field office, Springfield, Illinois.

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Q. Are you familiar with the Paragould Pharmacy in Paragould, Arkansas?

A. I am not.

Q. If in 2006 H.D. Smith would have reported a suspicious order of Paragould Pharmacy, would you have been made aware of that, reported a suspicious order to the DEA, would -- is that something that you would have been made aware of?

A. Not necessarily.

Q. Okay. I'm going to show you an investigative -- you've probably never seen any of these reports, but I'm going to show you the next one which is a similar report. That is Exhibit 8. And it is also involving the same entities.

In this report it suggests on it that H.D. Smith submitted a suspicious order analysis report for the month of April 2006.

Is that something that you would have been made aware of, also Paragould Pharmacy?

A. I am not familiar with the term "suspicious order analysis report." So I don't know what -- I don't know if that's a DEA report. I don't believe it's one of ours.

Q. Okay. That might just be the phrase that DEA is referring to.

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A. Okay.

Q. Suspicious order report from H.D. Smith.

It lists -- this DEA report identifies Paragould Pharmacy. And it -- it lists, as you can see, purchases of controlled substances.

You were in a compliance capacity at H.D. Smith at the time that this report was issued, right?

A. Yes.

Q. You -- you've never -- you are not familiar with Paragould Pharmacy in -- in Arkansas, I believe you testified, right?

A. Yes.

Q. So what was your role in the routing or reporting of suspicious orders to the DEA at the -- at the time that this report was received by the DEA?

A. Our operation managers would report to the field office in -- in their area, so in -- in this case it's -- it's our Springfield, Illinois distribution center. So our operations manager would have reported to Scott Garriott who is the diversion investigator in the field office. So looking at this report, I -- I -- I don't know what to tell you about it. I mean --

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Q. You have no -- no recollection about this?

A. No.

Q. Okay.

A. You know, as time went on, we had our operations managers send us reports any time they had contact with regulatory agencies, whether it was sending us a suspicious order or not. I don't know if that was in place at this time. But I do not recall Paragould Pharmacy.

Q. But earlier you referred to a manual system and then the automated system.

This would have been during the manual system at H.D. Smith?

A. Yes, sir.

Q. And at some point in time H.D. Smith changed its reporting of suspicious orders from the operations managers that you just described, is that right?

A. Yes.

Q. When it went to the automated system, who was responsible for reporting the suspicious orders?

A. It would have been me or someone designated on my staff. At the time when we put the

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automated system in place in 2008, it was just me and P.J. Little or VanDermeersch.
Q. And were you always reporting to the same person at the DEA or was it -- was it a different person each time or how did that work?
A. We were under instructions -- the CFR, the regulation says to report to the field office where the -- your distribution center is located. We were under instructions by DEA headquarters after we had gone up there in October of 2007 to report directly to headquarters. And there were -- there was -- there were several different people that we would have reported to, basic -- you know, based on who was in what position at the time, whoever we were told to send it to, but it was to DEA headquarters for a time.
Q. And how were these submitted, were these faxed, mailed, e-mailed?
A. E-mail.
Q. Was there a time when you were faxing suspicious orders to the DEA?
A. I'm an -- I -- I don't know.
Q. Okay.
A. I'm assuming that before -- before -- in 2008 when we had our automated system it was e-mail.

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I don't know how they were submitted by the divisions prior to that.
Q. Was there a protocol under the manual -- a policy, a procedure or protocol under the manual system which required internal copies of those reports to anyone else? I know you mentioned you didn't receive them, but did anyone else receive them?
A. Not that I'm aware of.
Q. Okay. I'm going to show you a one-page, Exhibit 14, so skipping over quite a few since -- just take a look at that.
Have you seen this e-mail before?
A. This would have been before my time at H.D. Smith, so I have not seen this before.
Q. Okay. I didn't know if -- if maybe your counsel had provided it to you or if you've seen it just in the course of business.
Okay. Do you recognize the -- the original sender of this e-mail, Danny Avila, Avila?
A. Yes.
Q. Do you recognize an Agent Barnes, it says: "We called Agent Barnes from our local DEA office."
Do you know who that is?
MR. PADGETT: I'm going to object to scope based

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on the exhibit's date.
You may answer.
BY THE WITNESS:
A. Well, Danny Avila was in Florida, so -- and I think that's Agent Barnes -- or so it would be a Diversion Investigator Barnes, and I -- if it's the same person, I know her, but I -- I don't -- without a first name, I know Barnes is kind of a common name, so...
BY MR. YOUNG:
Q. Okay. Danny Avila in the -- in the e-mail says in his last sentence:
"These orders would not be caught by the suspicious order utility since they were keyed in-house (is my understanding)."
Do you understand what Danny is referring to there? I understand this is before your tenure, but I just want to know whether you are familiar?
MR. PADGETT: Let the record reflect a continuing objection based on scope, date of the exhibit.
BY THE WITNESS:
A. I do not know what that is.
BY MR. YOUNG:

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Q. Okay.
The phrase "suspicious order utility," does that mean anything to H.D. Smith? Does that have a particular meaning?
A. I -- I don't know what that is. I have never heard that term.
Q. Okay.
The top part of the e-mail which is the -- I know the -- the headings are, I guess, cut off, this is just how it was produced to us, but it is from an Angelo Grande.
Do you know Angelo Grande?
A. Yes.
Q. Who is Angelo Grande?
A. Currently he is in charge of our Valley Wholesale division in Stockton, California. Prior to that he was vice president division manager of our Carson, California division, which before that was in Inglewood. And it was a -- an acquisition. So he came from an acquisition. I believe it was Barnes Wholesale that was acquired before my time.
Q. Okay. The second sentence of Angelo's response to Danny is:
"You are correct. It's my understanding

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also that all keyed items are excluded from the reporting utility and those items are reviewed manually with a report that is generated from the AS400, showing control drugs sales history by item, date, and by customer."

Do you know what he is referring to there by the AS400?

A. Let me read this through real quick.

Q. Sure.

A. I -- I don't know what he is talking about. I mean, I know what the AS400, that was our sys -- that was our, I don't know what you call it, our system, computer system, software companywide at the time.

Q. Who would be the --

A. I can't -- I can only speculate what it is. I don't know what it is.

Q. Okay. Who would be the person who would have the most knowledge about the AS400's suspicious order utility?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. I would have no idea. I don't think -- we haven't used AS400 since 2013, and I doubt there is

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anyone at H.D. Smith around anymore that would have any expertise in it.

BY MR. YOUNG:

Q. Who was in charge of compliance at the time of this e-mail?

A. Each -- each division was in charge of their own compliance.

Q. There was no central compliance function in headquarters?

A. Not that I'm aware of. I was first.

Q. Did -- I noticed that Dale Smith and Chris Smith are both copied on Danny's original e-mail.

Why would they -- I'm sorry. They are not copied, they are actually direct addressees.

Who on -- why would they be included in a compliance e-mail like this?

A. I have no idea.

MR. PADGETT: Object to form.

BY MR. YOUNG:

Q. Did Dale Smith, Junior have any -- I assume this is Dale Smith, Junior in this e-mail, is that your opinion?

A. It would be my opinion.

Q. Yeah. Did Dale Smith, Junior have any

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role in the compliance function of H.D. Smith at the time of this e-mail?

A. I don't know what his function was at this time.

Q. Do you know whether or not Dale Smith, Junior ever authored any compliance-related policies or procedures for H.D. Smith?

A. I believe there is one policy regarding orders.

Q. That was authored by Dale Smith, Junior?

A. Yes.

Q. Do you know whether Chris Smith had any role or involvement in authoring any policies or procedures relating to compliance functions?

A. Not that I'm aware of.

Q. If we were to try to seek through your information technology the either report or data attendant to the report that's referenced here, who would we be best to talk to about that? And you may not know. I just --

A. I -- I can only speculate. Rob Kash- --

MR. PADGETT: Let me reiterate my continued objection.

BY THE WITNESS:

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A. Rob Kashmer was the head of our IT at one time. I don't know if at this time.

BY MR. YOUNG:

Q. Okay.

The last sentence, and, again, I realize this is before your -- your tenure with the company, but the last sentence of Angelo's response is, and I'll -- and I'll read it:

"It's my understanding that this monitoring requirement is all a matter of alerting and assisting the DEA with abusers even though they are already getting some of that data on a regular basis through ARCOS."

What's the -- what is the reference to ARCOS there, what does that mean?

A. We report ARCOS data to DEA on a -- a monthly basis through all of our distribution centers. It is all of our C-IIs and C-III narcotic products that are either purchased -- you know, either we receive in or we distribute out. It is part of the closed loop system.

Q. And the date of this e-mail is October 5th, 2005.

Have there been any changes since the date

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of this e-mail with regard to the way H.D. Smith reports to the DEA on the ARCOS system?
A. We -- we have central reporting now through my office, through the corporate office.
Q. Was that part of the automated system that you've earlier described or is that something different?
A. No. It's -- it's separate.
Q. Okay.
I will now show you Plaintiff's Exhibit 15 with three highlighted sections on it. Take your time. I think that this is the -- the policy that you just referenced which was authored by Dale Smith, Junior, but I want to -- want to hear from you, so take a minute to familiarize yourself with it.
A. This was the one I was referencing.
Q. Okay. Was this the policy for controlled substance monitoring that was in place at the time you joined H.D. Smith?
A. Yes.
Q. I understand that this was written before you got there, but have you since getting there learned when this policy was authored? I think it's -- it's not dated.

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A. I have no idea.
Q. Do you know how long it was in place when you got there?
A. I do not.
Q. When you were hired at H.D. Smith, was part of your responsibility to take ownership over the policies and procedures relating to controlled substance monitoring?
A. When I was first hired?
Q. Yes.
A. No.
Q. So when you were first hired with H.D. Smith, you had no responsibility relating to controlled substance monitoring policies and procedures?
A. It was -- it was an evolution.
Q. Am I to understand your -- your initial focus was on security more than controlled substance monitoring?
A. Originally my title was director of security. It morphed into director of security and compliance. By it was more of, yeah, security-related audits of facilities.
Q. The policy that's contained within

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Exhibit 15 describes an operations manager as the controlled substances coordinator.
When did that definition or assignment to the operations manager end, do you know the particular date?
A. It would have been when we rolled out our -- our automated system which was rolled out throughout the spring of 2008 to our various distribution centers.
Q. This policy references what I would call paraphrasing of the regulations, and I'd just -- I'd like you to read that first paragraph that's highlighted there, "The monthly review"?
A. Read it?
Q. Yes.
A. "The monthly review will consist of comparing previous orders to determine frequency of ordering, size of orders on specific products and deviation from typical purchasing patterns. Evaluations will be made from these reports to determine if account should be brought to DEA's attention."
Q. So this was the policy that was in place at the time you began at H.D. Smith, right?

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A. Yes.
Q. Is H.D. Smith of the opinion that this policy complied or failed to comply with the Controlled Substances Act as of 2005?
A. Ask me that question again.
Q. Did -- did the -- this policy, the controlled substance monitoring policy, did this meet the requirements of the CSA or did it fail to meet those requirements?
A. We be --
MR. PADGETT: Object to form.
BY THE WITNESS:
A. We believe that it did.
BY MR. YOUNG:
Q. And I just want to reference back to your earlier testimony.
Do you mean to say that you believe that it met the requirements as interpreted by the DEA or under the letter of the law?
MR. PADGETT: Object form.
BY THE WITNESS:
A. Both. We were reporting orders when they were discovered. At this point it was discovered during the monthly reviews.

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BY MR. YOUNG:
Q. What's a -- a picker? This policy references experienced pickers.
What's the -- I don't know if that's a term of art, or what H.D. Smith...?
A. In a -- in a warehouse environment, it is the actual people that go to get the product for the order.
So in a -- in a work -- in a pharmaceutical warehouse, Schedule II products are kept in a vault, III through Vs are kept in a -- in a DEA-mandated cage. Only certain people have authority to go in those vaults and cages. We put our most experienced people in there to reduce errors and so we have consistency of people looking at orders that could possibly identify something that may be out of the ordinary.
And so the picker actually has -- in the old days it was paper, these days it is all electronic, but basically it's just picking the orders, you know.
Q. How would the picker determine whether or not an order was out of the ordinary or excessive or unusual?

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MR. PADGETT: Object to form.
BY THE WITNESS:
A. You know, our -- our pickers would -- again, they were the most experienced people, they had been there the longest, they had the -- that are the best at what they do, they are there every day filling orders, they see the orders come in every day, they see the customers, who the orders are for, and it was the expectation that if they saw something that they didn't think that was right they would then bring that to the attention of the operations manager or their supervisor.
Q. And if they didn't make that observation, if they -- if they failed to bring a otherwise suspicious order to the attention of the manager, is there some other mechanism in place at the time, this is going back to '05, that would have caught suspicious orders or unusual orders other than the pickers?
A. Not to my knowledge.
Q. Do you know how effective this policy was at H.D. Smith in identifying suspicious orders?
MR. PADGETT: Object to form.
BY THE WITNESS:

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A. We had orders that -- that pickers had identified as potentially suspicious that were reported and then the monthly reviews by the operations managers that were, again, familiar with the customers and, you know, we -- you know, and then they would -- if they saw something that -- that they thought may be suspicious, they would report it to DEA.
BY MR. YOUNG:
Q. If the DEA never had meetings in D.C. and Rannazzisi never sent those two letters, would H.D. Smith have continued this type of policy for controlled substance monitoring?
A. I can't speculate on that.
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. I just want to make sure I understand whether or not the DEA is what triggered the change in the evolution of your system or was it self awareness, self observation?
A. There is -- there is no regulation that says you have to have an automated system or a manual system. There is still people today, there is warehouses out there, there's people that have manual

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systems in place.
As evolution of -- of -- over time, you know, when we had our first meeting, you know, I started in November of 2005, had a meeting with DEA in January of 2006, we started to explore a -- an automated system so that we could constantly, you know, try to improve our processes to maintain effective controls against diversion. You know, the whole industry has evolved.
Q. This policy was in place until what, what time period?
A. I don't know that it was -- it would have been when we put a policy out in 2008 for order monitoring.
Q. Okay. And prior to the implementation of the 2008 policy, who -- who at H.D. Smith was responsible for monitoring controlled substances?
So this policy references operations managers and pickers. Was there an -- an -- was there anyone else that was involved in that process?
A. I -- I -- I can't -- I can't -- I can't say. I mean, the operations manager was the controlled substance coordinator. He was the one that was in charge of the warehouse, everything that went

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on in the warehouse, so he would have been, you know, the main person.
Q. Was there an internal auditing function that tested compliance with these policies and procedures?
A. Not that I'm aware of.
Q. When you came onboard, and I understand there is an evolution of your responsibilities, was there a point in time in which you tested or called into question the efficacy of this policy?
A. I don't know if it was to call into question. We were just con -- we were just always trying to him prove our processes and our procedures.
Q. So did you evaluate this policy from a compliance perspective?
A. I wouldn't say I evaluated -- I evaluated this policy.
Q. Were there, I'm going to use the word "thresholds," are you familiar with the word "threshold" --
A. I am.
Q. -- in the context of registrants?
Were there thresholds in place for pharmacy customers at the time of this policy?

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A. Not that I'm aware of.
Q. So the only -- what was the basis for a picker to determine whether or not an order was excessive? Just their memory of the prior month's order?
A. It would have been their knowledge of the -- of the customer, their ordering history, their day-to-day, everyday phone orders.
Q. I think you mentioned that this was a -- a very veteran person in the company, there was not much -- much turnover among the pickers?
A. Not to my knowledge, no.
Q. Was this a highly compensated position?
A. I don't know if it would be highly compensated. It was -- you know, there were veteran or, you know, experienced people that had had many years on, so I don't know exactly, you know, how they were compensated, if they got increases in wages when they went into the cage or vault. I can't answer that.
Q. How many pharmacy customers did each picker pick for in a given month? Was it -- did they have designated customers they always picked for or was it an order came in and you just handled that

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order?
A. They would handle the orders as they came in.
Q. How many customers did H.D. Smith have in 2005, approximately?
A. It would -- well, it would depend on what distribution center you are talking about. The Springfield or -- or --
Q. Nationally how many customers?
A. In 2005, I -- I don't have any idea. I -- we had -- I'm not even sure how many distribution centers we had at that time because there was a period of time where we were opening or making acquisitions or what have you.
Q. Okay. But if a picker doesn't have the regular customer that they are picking for each month, how is it that they are going to know whether or not an order on any given month is excessive? In other words, one month they may get Pharmacy X and the next month they may get Pharmacy Y, how can they compare the two?
A. Usually our customers order every day.
Q. Okay. So how is it that a picker -- is there some reference manual, is there some database,

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is there -- is there someplace for a picker to go when they get an order for a customer they are not familiar with to determine whether or not that order is unusual? And specifically I ask that because of your prior testimony indicating there was no threshold for these customers. So how -- how are they to know, what's the -- what's the basis?
A. I can't answer that.
Q. Okay. Let's see.
Do you know whether or not there was any training provided to operations managers for their role as the controlled substance coordinators?
A. What time period?
Q. In '05, it's admittedly prior to when you got there?
A. I -- I don't know.
Q. How about in '06?
A. I implemented training in 2006 after our -- our meeting with DEA in January of 2006.
Q. What type of training did you undertake for the operations managers?
A. It was mainly regarding orders related to internet pharmacies which was the basis of our discussion in 2006, January of 2006 with DEA. I

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used -- I may have used their whole PowerPoint that they presented to me in addition to other information I would have had to try to educate them on looking at -- at orders that may be suspicious.

Q. That PowerPoint, do you know if it was shared with them via e-mail or was it something that you put on live on the screen?

A. I went to each distribution center.

Q. Do you know what the budget was for compliance in 2006?

A. I don't. I wasn't in charge of the budget.

Q. In terms of the process of the operations manager making decisions, did the operation managers have access to data, a database or a system that they could use to compare prior months' orders?

A. I believe the way that -- the way that their reports came out at the end of each month they would have access to monthly reports on controlled substances purchased by our customers. So they could reference previous months if they wanted to.

Q. And was there any type of formula or algorithm used by the company to determine whether or not an order was excessive as compared to prior

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months?

A. Not at that time.

Q. But at some point I guess with the role of the automated system there was a calculation or algorithm?

A. Yes.

Q. And we'll -- we'll talk about that in just a sec.

Do you know whether or not there were -- other than the -- the typical monthly review that's contemplated by this policy, were there ad hoc reviews done by operation managers of pharmacies?

MR. PADGETT: Object to form.

BY MR. YOUNG:

Q. For -- for purposes of the controlled substance monitoring, I should mention.

MR. PADGETT: Same objection.

BY THE WITNESS:

A. I -- I don't know. You know, I was in communication with -- with the operations managers. What we discussed, if I -- we discussed certain accounts, I -- I just -- I'm not -- I can't tell you. I can't remember.

BY MR. YOUNG:

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Q. And at the time of this policy, while this was in place, it was the practice of H.D. Smith to ship orders and later review whether or not they would be reported to the DEA.

Is that accurate?

A. It was a policy that if -- if pickers would identify orders beforehand they could be reported to DEA as suspicious, but also, you know, as the policy says, there was a monthly review, as was industry standard and the expectation from DEA.

Q. But the -- the order that the picker identified, was that shipped or was that held?

A. You'd have to be more specific on what -- what our -- it would more like -- my understanding, it would be held until we would discuss it with DEA.

Q. Was that in the policy somewhere?

A. I think it's in here somewhere about discussing it with DEA field office.

Q. Yeah, I think the --

A. It is right below your highlighted --

Q. Yeah.

A. -- part on the second page.

Q. Yeah, let's -- let's dig into that a little bit.

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There is a -- a highlighted portion that -- can you read that for us?

A. On Page 2?

Q. Yes.

A. "If while picking, an excessive purchase is discovered it will be brought to the attention of the Controlled Substance Coordinator. A check with the local DEA office will be made before shipping of the individual order."

Q. So there was a policy in place at the time, this policy, that says if you identify an excessive purchase, check with the operations manager who is the controlled substances coordinator, right?

A. Correct.

Q. And it doesn't really say who. I assume it's the operations manager. It says: "A check with the local DEA office will be made before shipping of the individual order."

That's your recollection of what took place in 2005?

A. That's my understanding. And I think --

MR. PADGETT: Object to form.

Go ahead.

BY THE WITNESS:

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A. -- that's what's in the policy.
BY MR. YOUNG:
Q. Do you know how long it took to hear back from the DEA when you reported suspicious orders at the time?
A. To my knowledge, we would never hear back from DEA.
Q. Okay. So if you were to check with the DEA before shipping and you never heard back from the DEA, I take it that, then, the order never shipped?
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. Is that accurate?
A. No, that is not necessarily true.
A check with the local DEA, that would -- in my mind that means you would call the DEA, check -- in this case you would try to talk to Garriott and discuss the order with him. Now, I wasn't there. I don't know exactly what happened, but that's -- that would be my assumption.
And then it says, you know, in the next -- next paragraph: "If" -- "If the local DEA office cannot be contacted before shipping, it should be brought to their attention as soon as possible."

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So it was still the expect -- the -- the -- the expectation of the DEA and the way this policy is written is that, you know, that -- that order, if they could not get ahold of the DEA to discuss it with them, my assumption is it would be shipped and then discussed with DEA at a later time.
Q. And this policy was in place for part of your initial tenure with H.D. Smith, right?
A. It was.
Q. So from the time that you got to H.D. Smith until you implemented the new policy, what you just described is what occurred, right, that the order would -- would be shipped?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. It depends on what the circumstance was and if they were able to get ahold of -- of Garriott, and I don't know if the order was -- first of all, you'd have to be specific on what order and I don't know if it was shipped or it wasn't.
BY MR. YOUNG:
Q. Yeah. And I'm --
A. I'm only going by the policy.
Q. And admittedly I'm speaking in

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generalities. I want to understand what H.D. Smith did generally.
So when -- under this policy when a picker identified an excessive purchase and brought it to the attention of the controlled substances coordinator, who was the operations manager, it was the policy to check with the DEA office. And what I want to know is, prior to the new policy, under this policy, whether or not generally orders shipped or did not ship? If you can't say, you can't say.
A. I -- I don't know.
Q. Yeah. Okay.
I had previously showed you some -- some DEA investigation reports. I know you weren't familiar with them, but those order -- those investigation reports indicated that those orders which were reported as suspicious had, in fact, been shipped.
Does that surprise you or is that consistent with your recollection of what occurred at H.D. Smith prior to implementation of the automated pol- -- policy?
MR. PADGETT: Object to the form.
You can answer.

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BY THE WITNESS:
A. It wouldn't surprise me. You know, the enclosure down here says DEA purchase report, you know, for a month's time, and -- and this is a period later, so I'm assuming that they were shipped. I don't know for a fact.
BY MR. YOUNG:
Q. Okay. Do you know whether or not there was consistent implementation and execution of this policy at each of the distribution centers?
MR. PADGETT: Object to form, scope.
BY MR. YOUNG:
Q. From -- from '05 to '08?
A. That was the expectation.
Q. But you didn't test or verify whether or not each of the distribution centers was complying with this policy?
A. No.
Q. Was there anyone charged with auditing or testing whether or not there was compliance with this policy?
A. Not to my knowledge.
Q. Do you know whether or not operations managers prior to your PowerPoint training were aware

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of the statutory definition of suspicious orders?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I would have -- I would have no way of knowing that.
BY MR. YOUNG:
Q. Really what I'm asking is, other than this policy, was there any other information that was given to operations managers about compliance with the Controlled Substances Act reporting requirements?
A. Prior to me arriving there, I do not know.
Q. How about after you arrived and except your PowerPoint instruction?
A. Well, I conducted an annual compliance meetings at all of our distribution centers.
Q. The -- you -- H.D. Smith maintained a Louisville, Kentucky distribution center during this time.
Is that accurate?
A. Which time period?
Q. '06 through '08.
A. I don't think the Louisville distribution center opened until 2007.
Q. Okay.

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A. I don't know the exact date.
Q. Fair enough.
Do you know whether or not the Louisville, Kentucky distribution center would have been the center to ship into Ohio, the State of Ohio?
A. Again, it would depend on the time period. Prior -- I don't know --
Q. Let me rephrase it.
A. It would depend on the time period.
Q. Let me rephrase it.
In 2007, where would Ohio pharmacies who are customers of H.D. Smith have obtained their products from, which center?
A. It would probably, and I don't even know if they had Ohio customers in 2006, but it would probably be Illinois or Louisville.
Q. And do you know today where Ohio customers get their products from?
A. More than likely Louisville. They could be some coming from New York metro and -- and Illinois could have some and we used to have a Smith Medical Partners that's no longer around that would have shipped possibly into Ohio. They were licensed in Ohio.

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Q. After an operations manager made a report to the DEA about a suspicious order, do you know whether or not they would inform the pharmacy customer of that report to the DEA? Was that --
A. The practice was to not.
Q. But it's possible that they did have those conversations?
MR. PADGETT: Object to the form.
BY THE WITNESS:
A. I highly doubt it.
BY MR. YOUNG:
Q. Do you know whether or not the sales -- I'll refer to them as the sales staff.
Does H.D. Smith have sales staff?
A. Yes.
Q. Do you know whether or not the sales staff enter -- whether or not the sales staff ever intervened on behalf of a pharmacy customer to prevent the reporting of a suspicious order?
A. Not to my knowledge.
Q. Okay. Moving right along.
MR. PADGETT: What time do you want to break for lunch?
MR. YOUNG: Oh, what time is it?

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MR. PADGETT: It is 12:05 right now. But if you go to 12:15, that would be another hour, hour-and-a-half block.
MR. YOUNG: I'm just trying to see where we can find a nice, natural break here. I guess we can -- I guess let's do it now. How long have we been going since the last break?
MR. PADGETT: About an hour.
MR. LEEDER: A little over an hour.
MR. PADGETT: About an hour and ten.
MR. YOUNG: All right. Let's do it. We have to keep the witness fed.
THE VIDEOGRAPHER: We are off the record at 12:04 p.m.
(WHEREUPON, a recess was had from 12:04 to 1:02 p.m.)
THE VIDEOGRAPHER: We are back on the record at 1:02 p.m.
BY MR. YOUNG:
Q. Mr. Euson, we just broke for lunch.
During lunch did you have occasion to speak with your counsel?
A. I did.
Q. Did any of the communications between you

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and your counsel affect or impact the testimony that you've already provided?
A. I wanted to make a clarification on a previous testimony.
Q. Okay. We'll get to that in a second.
A. Okay.
Q. Did any of the communications with your counsel serve to prepare you further for the rest of the deposition for 30(b)(6) purposes?
A. No.
Q. There was no preparatory comments or get ready for this or expect this?
A. No.
Q. So you mentioned you wanted to clarify something. What is it?
A. You had asked me about West Virginia and I had -- I had misspoke and I wanted to clarify. I said it was a fine in West Virginia. It was a settlement with no admission of any wrongdoing.
Q. And that's your recollection or your attorneys informed you of that?
A. Well, I asked them for the clarification.
Q. Were you involved in the, I don't want to say the legal aspect of it, but were you as the chief

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compliance officer personally involved in the settlement that was negotiated between the West Virginia AG and H.D. Smith?
A. I was not.
Q. Okay.
Okay. So, where we left off was sort of the first generation of your compliance process and policies and we called that the manual phase, I think, or the manual program, prior to the automated program, right?
And so I want to now veer into the automated program and -- and learn a little bit about that.
The -- when was the first instance in which H.D. Smith determined that it needed to create an automated program?
A. When you say "needed," do you -- do you reference that as some type of a requirement?
Q. Let me -- let me rephrase it.
When did H.D. Smith decide that it wanted to create an automated compliance program?
A. Probably mid 2006.
Q. And what were the factors that H.D. Smith considered in making that decision?

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A. To develop a better process and procedure.
Q. Did H.D. Smith determine that it was -- its current practices were in violation of the Controlled Substances Act without implementing an automated system?
A. No.
Q. So H.D. Smith could have, if it so chose, have continued with the manual version of its compliance program without violating the CSA?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. There is no -- there is no regulation that an -- that an auto monitoring system has to -- or program has to be manual or automated.
BY MR. YOUNG:
Q. And -- and I want to be clear in my question. I'm not just referring to the manual versus automated functionality, but all of the elements of what H.D. Smith did in complying with the CSA prior to implementation of the automated program, when H.D. Smith made the decision to go to the automated program, did it determine whether or not its existing or prior program was in or out of compliance with the CSA?

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MR. PADGETT: Object to form.
BY THE WITNESS:
A. We were -- we were in compliance with CSA. We wanted to improve the process.
BY MR. YOUNG:
Q. Okay. So H.D. Smith has never violated the Controlled Substances Act?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. What part of it?
BY MR. YOUNG:
Q. Any part of it.
A. Not to my knowledge.
Q. Okay.
A. No.
Q. The -- when did the -- I'm going to call it the CSOMP program, and I don't mean to -- to coin that phrase, but I think that's the phrase that H.D. Smith uses, right?
A. It is for our automated system.
Q. And what does CSOMP stand for?
A. Controlled Substance Order Monitoring Program.
Q. When was that program live, when did it go

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live?
A. It was -- it was rolled out to our different DCs in the spring of 2008, I believe, from beginning of March through the end of May. I don't have the exact dates, but it was by divi- -- you know, division by division.
Q. Do you -- do you recall which division you rolled out to first?
A. I'm sure it's documented somewhere, but I can't recall off the top of my head.
Q. No worries. I figured I'd ask.
And I want to understand a little bit about how you came to develop the elements of the CSOMP.
Are you the principal architect of the CSOMP system?
A. Yeah, I didn't -- I didn't do the actual IT work or anything, but yes.
Q. And what -- what reference materials did you use to develop the CSOMP system?
A. Early on we -- we -- we took a lot of what similarities to what AmerisourceBergen was developing, you know, in conjunction with, you know, guidance from the DEA in 2007.

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Q. Who was it at AmerisourceBergen that you communicated with regarding the development of CSOMP or what they were doing with their version?
A. I would have talked occasionally with Chris Zimmerman.
Q. And what was his title or role at Amerisource?
A. At the time I think he was vice president of corporate security and regulatory affairs.
Q. Did he share with you the details or the content of what went into their system?
A. More of the concept, not specific details. At the same time I was in communication with -- with Kyle Wright at the DEA. I believe Kyle Wright and -- and head of diversion at the time Mike Mapes, were working with AmerisourceBergen on that also, so it -- it was more a conceptual, not the specific details of it.
Q. Are you familiar with a -- a document called the Chemical Handler's Manual?
A. I am.
Q. How -- how do you know the Chemical Handler's Manual?
A. It is a manual concerning List I

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chemicals, and also at the time, again, you have to reference the time period, at the time there was a part of the Chemial -- Chemical Handler's Manual that referred to suspicious orders and a loose template on -- regarding that.
Q. Was the Chemical Handler's Manual something that Amerisource had relied upon in developing its system, if you know?
A. I do not know that.
Q. Is it something that you discussed with Mr. Zimmerman from Amerisource?
A. I don't recall.
Q. I'm going to show you what was premarked as Euson Deposition Exhibit 21. It's -- frankly, it's an excerpt. We don't have the full manual. There is a -- a cover page and then there is an Appendix E-3. I'll show you that.
MR. PADGETT: Sorry. Which exhibit?
MR. YOUNG: 21, I believe. It should be.
Yeah. Here you go.
BY MR. YOUNG:
Q. Does that exhibit look familiar to you?
A. Yes.
Q. The Page 2 of the exhibit, Appendix E-3,

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it -- it's a list of terms and definitions.
Do you know whether or not these terms and definitions were considered in H.D. Smith's building of its automated CSOMP program?
A. Can you give me a second to read this?
Q. Sure.
A. We used this formula, for better terms, as a guideline, because it was the only thing out there that was produced by DEA that referenced calculating possible, you know, orders that may be suspicious. So we used it as a guideline.
Q. Okay. And when you say "we used it as a guideline," are there particular aspects of it that you used it as a guideline or it -- it lays out in -- in Sections 1 through 5, I think, the formula you were referring to, is that -- is that what you mean when you used it as a guideline or is there something different?
A. Well, again, this came out of the Chemical Handler's Man -- Manual which is specifically for list chemicals, not controlled substances. But there is reference to, excuse me, for, you know, C-II through V controlled substances in -- in the -- in the notes.
So we used this, again, as a guideline,

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that's as far as how we originally identified our customers' purchasing, you know, and then we used a three times factor in some of our calculations when we put our system together. So we -- we didn't use this verbatim because it -- it -- it mixed -- it mixed chemicals with -- with controlled substances. We took pieces of it out and used it as a guideline.

Q. I gotcha.

But you did adopt the three times multiple for your basis for identifying suspicious orders?

A. For our basis of identifying potential orders.

Q. Okay. Prior to the implementation of your automated system, your CSOMP system, did you have established customer thresholds that they could order?

A. Before CSOMP?

Q. Yes.

A. Yeah, I think it does describe before that we did not.

Q. I just want to make sure.

And part of the implementation of CSOMP was creating customer thresholds, is that correct?

A. Yes, that was one of the things that we did with the system.

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Q. And I'm just sort of taking your prior testimony and your testimony about the adoption of the Chemical Handler's Manual.

Am I to understand that H.D. Smith used the historic purchases of its customers for controlled substances, multiplied times three to determine whether or not an order is potentially suspicious?

A. That's a little bit too general.

Q. Okay.

A. Because it was a little bit more specific on how we did it.

Q. Okay. Can you walk us through specifically how H.D. Smith determined whether or not a customer was submitting a potentially suspicious order?

MR. PADGETT: I'll object to form.

BY THE WITNESS:

A. We, again, had taken the -- taken this as a guideline, taking what we knew of -- of the way AmerisourceBergen was developing their system. First of all, we -- we created families of controlled substances.

BY MR. YOUNG:

Q. Okay. Let me -- let me stop you there.

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A. Okay.

Q. We'll -- we'll just kind of build it as we go.

When you say "families," what do you -- what do you mean?

A. Different types of controlled substances, such as oxycodone family, hydrocodone family, methadone family, morphine. So we had, I believe, at the time when we first developed this, I think we had something like 28 different families of drugs.

And the reason we did this -- well, first of all, it was one of the things that Amerisource was doing -- and any time that we had discussions with DEA, it wasn't all controlled substance, it wasn't all opioids, it was -- it was pretty specific to your oxycodone, your hydrocodone. So we tried to silo those into -- into families of all types products in that family. You know, like oxycodone would include OxyContin, generic oxycodone, Percocet.

Q. Okay. So you break down the drug purchases by family, and then what goes into the process for determining potentially suspicious orders?

A. One of the other things we did was we did not have the ability in our system to differentiate

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between class of -- of DEA business activity, whether pharmacy, hospital, in the sys- -- systematically in our CSOMP system. So we arranged customers by monthly sales volume. And I believe there was -- again, I could look at the documentation, but I think it was 10 or 12 different types of monthly sales volume where it would be customer from zero to -- that buys from us from zero to $10,000 in a month, all products, and then 10- to 25,000, and so on, to get basically a -- group customers as a particular size of customer and -- and volume of business that we would get from that customer.

Q. And that was also something that was new to H.D. Smith, you hadn't done that in the manual system, right?

A. No.

Q. And you hadn't used families under the manual system either?

A. Not specifically, but I think the -- the reports that the managers went through every month, they were grouped somehow. I got all controlled substances. I don't know if they were grouped alphabetically or by different classes, but there would be a -- it would have been the first time we

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would have defined customers by volume and defined families of drugs.
Q. Okay. So you got the customer size and type and you've got the families.
What are the other factors that went into determining whether an order was potentially suspicious?
A. These are factors on how we designed our system.
Q. Okay.
A. Not factors that pointed to a suspicious order.
Q. Got you.
A. A potentially suspicious order.
Q. Let's -- let's go into building the system first.
A. Okay.
Q. So what else went into building the system?
A. Well, and then we -- we did similar to what they -- again, using this as a guidance, customers within, if I can use just an example, if -- if we had a dozen customers within a certain revenue class, whether it be -- I'm getting ahead of myself,

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too. I've got -- when I say we have 28 drug families, those were also further broken down by dosage form, whether it be a pill, a liquid, a vial, powders, so that we could compare apples to apples, basically.
Q. Okay.
A. Then -- so if we -- if we had a -- make it just easy numbers. We had ten customers that were within a -- a revenue class of 25 to $50,000 a month, we would take those, those 12 customers -- or ten customers as an example and look at all of their controlled drug purchases for the previous 12 months and come to an average within that -- within that revenue class, we call them.
So it may be if -- if that average, say, for hydrocodone was, you know, 5,000 dosage units in a month, the average that those -- then we would add a -- multiply a factor of three onto that and that would be the threshold.
Q. Okay.
A. That moved and changed every month because customers were coming and going out of revenue classes and volumes differed.
Q. Sure. Under -- understood.
But that was the original -- the original

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basis was what you just described and it could change over time with the purchases of the pharmacy customer?
A. Yes.
Q. Okay. Why did you work with Amerisource as opposed to any other competitor in that space, like a Cardinal or McKesson or others?
A. We knew that -- I knew that Amerisource was working with DEA on their system. I was at the conference when they did a co, you know, DEA and Amerisource doing a -- a -- a presentation on their potential system that they were building, and so if it was -- you know, again, DEA does not give a blessing to any system and they won't tell you they will, but I knew they were working with DEA, so that was as close as we could get and -- and, again, using the -- the Chemical Handler's Manual, because it was the only document that gave any guidance at all as far as a potential threshold system and an automated sys -- an automated system.
Q. Do you know --
A. And this is no longer in the Chemical Handler's Manual.
Q. Okay.
Do you know whether or not Cardinal or

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McKesson similarly adopted CSOMP systems of their own at that time?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I don't know.
BY MR. YOUNG:
Q. Were you a member of the Healthcare Distribution Management Association at the time?
A. I was.
Q. Did you serve on any committees or subcommittees or boards or panels for the HDMA?
A. I was on two committees, regulatory affairs committee and the state government affairs committee.
Q. And did your work on those committees touch upon the development of these types of systems, the CSOMP system?
A. It -- it did. Again, there was -- as I stated before, there was no -- there is no system that DEA endorses. There is no -- there was no template for it. And -- and -- and even with a trade association, you've got antitrust issues and such as far as how much you can discuss with competitors.
Q. Were there representatives from

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Amerisource on the committee that you described that touched on this compliance work?
A. I believe Chris Zimmerman was on that.
Q. Were there representatives from McKesson on that committee?
A. I believe so.
Q. Were there representatives from Cardinal?
A. I believe so.
Q. And so did you meet regularly as a committee?
A. There were periodic calls and there was a one-time-a-year face-to-face meeting that sometimes I made, sometimes I didn't, and other members the same way.
Q. Were there other representatives from H.D. Smith who would attend a committee meeting in your absence?
A. Again, it depends on the time period. There were other people in my position when I was not at the company and there were other people that were -- could have gone to those meetings and in lieu of me going.
Q. I'm going to show you what was premarked as Euson Exhibit 22. It's a longer document than

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we've been handing you. So it might take you a bit to look at it.
Let me know if you are familiar with this document?
A. I'm familiar.
Q. How are you familiar with this document? Where do you know it from?
A. It's from HDMA.
Q. Did you have a hand, through your committee work, in creating this document?
A. I believe that the -- I -- I don't even know which committee. It may have been the regulatory affairs committee that may have had a hand in -- in -- in this. I know they also worked with some outside consultants.
Q. Do you recall receiving drafts or participating in the drafting yourself of this end product?
A. I probably did. I can't say specifically.
Q. Do you know whether or not the CSOMP system that H.D. Smith implemented in the spring of 2008 met the guidelines that HDMA developed in this document?
MR. PADGETT: Object to form.

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BY THE WITNESS:
A. I would have to study this again and get into the weeds with it to --
BY MR. YOUNG:
Q. All right. Let's -- let's walk through a little bit of the document.
A. Okay.
Q. So let's turn to page -- I think it's -- keep going -- page, what page is that? 6 of 13. There is a Roman numeral section: Monitoring for Suspicious Orders, System Design.
A. Monitoring for Suspicious Orders?
Q. Yes.
A. Okay.
Q. Okay. So that section, it looks like it says: "It is recommended that a distributor develop an electronic system..."
H.D. Smith did that, right?
A. Yes.
Q. "...with accompanying written standard operating procedures."
Do you know whether there were SOPs at H.D. Smith at the time the CSOMP rolled out?
A. We did develop SOPs at the time.

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Q. Okay. The specific elements of the system are described below that, Section (a), and the first one I think is what you earlier described, which is: "Separate, classify or group customers into appropriate different classes of trade."
Did the CSOMP program do that?
A. No. The vast majority of our customers were pharmacies. We had one division of ours that sold mainly to doctors and clinics. So I -- I -- I can't -- we -- we did not have it separated by, like, DEA business activity.
Q. Did the system evolve to include this, like does it include it today?
A. No.
Q. Okay. Because it is such a small part of the business, is that why?
A. I can't tell you why our system doesn't identify it.
Q. Okay.
All right. Let's flip the page. The next section, let's just pull this down here, it says:
"A distributor may use the DEA website to obtain the DEA's designation of a drug's controlled substance code number to aid in developing a drug

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family."
I think you previously testified that you did do that, that CSOMP did -- did identify families?
A. Families, yes. We didn't necessarily use the controlled drug code number.
Q. What did you use to develop the drug families?
A. It was basically the generic ingredients that were within the product, such as if it was a Percocet, which is oxycodone and acetaminophen, we put it in the oxycodone family.
Q. So, but beneath that bulleted point there are some other options to identify families and I -- I didn't know if you had used one of those to develop your -- your system.
The second one is using the NTIS system or the NDC number for the active ingredients.
Do you recall?
A. We -- we originally, when we beta tested our system in 2006 and '7, we tried to use the NDC code, and there are so many variables of the same drug using the NDC code it became unusable in our --
Q. Okay.
A. -- system.

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Q. Okay. Section C is: "Develop thresholds to identify orders of interest."
I think you testified that you did develop thresholds based in part on the Chemical Handler's Manual, is that correct?
A. Yes.
Q. The third paragraph of this section says: "Distributors are encouraged to update these quantities for determining averages by evaluating schedules, products or families of products and other information made available by the agency to determine an appropriate benchmark for identifying controlled substance orders of interest."
That's not so much of a system expectation as it is a sort of policy or procedure expectation of H.D. Smith.
Do you know whether or not H.D. Smith took that into consideration?
A. Our system was -- was constantly evolving. When we first developed it, it was strictly a three times multiplier on -- on those products. Based on customers' needs, based on a number of factors, site visits, dispensing reports, things like that. We -- our attempt was to customize thresholds for customers

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based on their individual needs.
And so, again, it was an evolution where we went from a -- a strict three times multiplier to where we could add or subtract multipliers, and then, again, as -- as we kept evolving, we were able to add static thresholds to certain customers on -- on drugs based on their legitimate needs.
Q. Can you put some date connection to these changes in the system, if you recall? So let's -- let's start with the first change.
The system began with a three times multiplier. What was the first change to that three times multiplier, when did that occur?
A. It had to have been after I came back, because I left -- after we rolled out CSOMP to our last distribution center, I left about a month after that.
Q. Okay.
A. So it would have been sometime after I came back, so sometime in 2009.
Q. Did the change to CSOMP when you returned, was that because of something that you learned when you were away from H.D. Smith?
A. No. It was -- it was more trying to

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constantly evolve and -- and make our system better and -- and better meet our -- our customers' needs and -- and their legitimate, you know -- you know, sup- -- supply of drugs.
Q. One of the examples that this HDMA guidance document includes is the geographical area, the uniqueness of the geographical area.
Is that something that your CSOMP took into account?
A. It did. When we -- I told you that we -- we rolled out our CSOMP division by division and they were in various regions of the country, and we used the customers' data for the division for our thresholds.
So if you -- I can give you an example. The example I was using before of ten customers within a 10- to $25,000 revenue range, if it was a -- if it was the Kentucky division, we used the -- the customers that were serviced by the Kentucky division, if it was in Illinois, we used the customers that was serviced by our Illinois division. So we were trying to regionally identify the needs of our customers.
Q. At some point did you move away from that approach or is that how it is today?

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A. We did. Now we do it on a national basis.
Q. Why is that?
A. We thought it -- it -- it helps us to identify potential orders of interest, more to find -- so we don't incorporate, I guess, different areas of the country that may be experiencing issues with certain drugs more than others and we didn't want that to be influenced in our system as a whole.
Q. When was the first time that that change was incorporated into the system?
A. I'm not sure. It would have been before I left in 2013, but I just don't -- I don't have the specific date. I could find it, but I just --
Q. Do you -- that's okay.
Do you know the geographic area that -- or areas that you considered in -- in making this change? In other words, was it one part of the country that you thought was skewing things or was it multiple parts?
A. It was -- it was different parts of the country and different drugs that were at issue.
Q. Do you recall which parts of the country it was?
A. You know, Florida had a -- an oxycodone

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problem, not a hydrocodone problem. The Houston area in Texas had a hydrocodone problem. Middle Tennessee, you know, had an oxycodone problem. California had a hydo -- a hydrocodone problem and promethazine with codeine problem.
So we tried to keep track of the different issues in different areas and tried to -- again, we were always trying to improve our -- our system and the processes that we were using.
Q. Do you recall if Ohio was one of the geographic areas that had a problem that was considered here?
A. Where specifically in Ohio?
Q. Anywhere in Ohio?
A. There is -- down in the southeast portion of the state, Portsmouth area was a problem, Columbus area was a problem.
Q. And how did you determine that the southeast part of Ohio was a problem? What was the basis for that conclusion?
A. Research --
Q. What --
A. -- news articles. You know, I -- I get daily feeds from Google alerts, you know, on -- on

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various things. There is books out about it. There is a -- there were certain physicians, practitioners that we identified in certain areas of -- of the country. And where we found those practitioners with what we would consider questionable prescribing habits, that's where there would be issues.
Q. And you said this was in 2013?
A. When we made the change?
Q. Yes.
A. I -- I am getting on that.
Q. Okay. I won't hold you to it. I don't -- I don't want you to guess.
So let's just pull this down here. Going on to Page 8 of that guideline document from HDMA, it -- it also says that:
"Distributors are encouraged to consider the following when developing 'thresholds.'" And I just want to tick down this bullet list to see if HDA -- if H.D. Smith incorporated these considerations.
The first one is: "Quantities of products the dispenser initially indicated during the 'Know Your Customer' due diligence phase it expected to purchase."

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Was that something that the CSOMP took into consideration?
A. That wasn't necessarily CSOMP, but a part of our overall due diligence process, we had what we call a customer profile that is basically a questionnaire. We call it a customer profile. That is, our sales reps were responsible for bringing that to their pharmacy customers, having them fill the questionnaire out, which did include, you know -- you know, what they expected to be purchasing from us, what type percentage of controls, a number of questions. I mean, there was -- there was a lot of questions that were asked on the -- on the form.
And then our sales reps also took various photographs inside and outside the pharmacy so we knew what it looked like, what -- what kind of area it was in, what -- if it was a brick-and-mortar building.
Q. And I -- and I suspect some of these other bullet points may be what you are describing, but the second one is: "A minimum of six months sales history and a maximum of 24 months sales history are recommended."
Was that part of your routine?
A. No. We -- well, it depends and it

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depended on when you're -- a lot of that, if -- if we were bringing on a customer from another wholesaler, we may not have that information. You know, as -- you know, as, you know, time -- time went on and we evolved our system, we started working more with dispensing records, dispensing information so that we could actually see what a pharmacy was dispensing, not just what they may be buying from us but what they -- what their total book of business was.

Q. Was it common for pharmacies to purchase controlled substances from more than one distributor?

A. Yes.

Q. Would -- would it also be common for distributors to discontinue doing business with customers that order too much controlled substances?

A. What do you mean by too much?

Q. Suspicious orders. So if a distributor like H.D. Smith determined that its customers were submitting suspicious orders, would H.D. Smith discontinue doing business with that customer?

A. It was commonly our practice that if we identified orders that were suspicious and we reported them to DEA -- and part of our investigation, again, would be to go to the pharmacy, get dispensing

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information, you know, launch an investigation. And I would say more -- more times the norm would have been that we would discontinue controlled substances to that pharmacy if we had reason to believe there may be diversion going on.

Q. And do you know whether or not that pharmacy would seek to obtain the controlled substances that it sought from H.D. Smith from another distributor? In other words, was there communication among distributors about these suspicious ordering pharmacies?

A. No. There were -- at one time DEA was sending out a list of pharmacies that other wholesalers had either closed or declined to do business with. That practice was discontinued after a short time.

Q. Okay. Turning back to this guideline, Section (d) talks about -- (d) talks about "Cumulative Reviews Or Thresholds." It says:

"The system should contain a mechanism for periodic review of cumulative orders from the same customer over time, to evaluate trends in purchasing patterns."

Did the CSOMP system or policies and

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procedures of H.D. Smith relating to CSOMP incorporate that?

A. Let me finish reading the rest of this.

Q. Sure.

A. This wasn't a -- a function of our CSOMP program but a function of our continuing due diligence on our customers. We had originally under -- we were under the -- you had mentioned, we had talked about the AS400. We were under that system until September of 2013 and then we went to an SAP system.

We also had some business analytic programs available to us. So we were able to run purchase reports and -- and run those and -- to give us that information, percentage of controls to non-controls. We regularly ran those on our customers, you know, who are our top -- top customers on percentage of controls, and then, again, regularly deal with dispensing information because we not -- we -- we -- we don't always know -- there is no way for us to know other controlled substances that are being purchased by a pharmacy through another wholesaler. And what gives us insight into it is doing dispensing reviews so we can see what they've actually dispensed. We still don't know what they've

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purchased, but we can see what they've dispensed.

Q. The ratio of controls to non-controls, was that a standard ratio that you looked as a barometer or did that change over time?

A. It depended on the -- on the customer. DEA has published an average controlled substance figure which is -- it is usually around 13 percent, but that's an average pharmacy, average is average. There is always going to be someone below and someone above.

So we -- you know, we used that kind of as a -- we knew that's what the average was. In different discussions with DEA and different presentations we kind of -- kind of morphed to a 20 percent controlled substance ratio that was more of a -- Hey, if you are over 20 percent, you know, let's take a deeper dive and look at this customer.

Q. Okay. So if someone was over a 20 percent ratio of controlleds to non-controlleds, that would trigger a deeper dive?

A. It could trigger a -- a review. And, again, it depends on the customer, where they are at, what their business is, who they -- you know, who -- where they are getting their prescriptions from, are

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they a -- you know, are they in a hospital campus, are they a mom-and-pop on a -- on a street corner. So it -- it all depends on -- on the individual pharmacy.

Q. What type of evidence would exist in H.D. Smith's records that would allow us to discern whether or not a pharmacy was subject to a deeper dive for being over the 20 percent?

A. We have due diligence records on all of our customers.

Q. Okay. So if we were to look at the due diligence documents for a pharmacy that was at some point in time over 20 percent controlleds to non-controlleds, we should see some record in the due diligence file of an evaluation?

A. I -- I can't tell you that there would always be one there.

Q. But there --

A. We did -- we did these, these were -- these were manual processes that we went through to identify customers that we could have -- you know, there may be a concern.

Q. There was no automation of this in the new CSOMP system?

A. It was not a part of CSOMP. It was --

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that was different.

Q. Is there any --

A. The audit was orders.

Q. Sorry.

Is there any automation of this process now?

A. No, other than periodic reviews.

Q. Okay. The next section, Section (e) talks about stopping shipments of orders of interest. It says:

"If an order meets or exceeds a distributor's threshold, as defined in the monitoring system, or otherwise characterized by the distributor as an order of interest, the distributor should not ship to the customer, in fulfillment of that order, any units of the specific drug code product as to which the order met or exceeded a threshold or as to which the order was otherwise characterized as an order of interest."

It is a rather long sentence that basically says you shouldn't ship controlleds to people that are over their threshold.

Is that true?

A. Not exactly how you just characterized

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that.

Q. Okay. How would you characterize that?

A. Our system is designed --

Q. Let me -- let me direct your attention. I just want to understand what the recommendation from HDMA is in this guideline.

A. Yeah, I'm going to get to that.

Q. Okay.

A. Our system is designed any -- any time if an order would hit a threshold, say I can use, for example, oxycodone, our -- a pharmacy exceeds the threshold for oxycodone, then that order would be held in our system and not shipped and any subsequent order of oxycodone would also be held. And that order will not be released until we either determined that -- you know, we -- we consider that a held order, an order of interest, not a suspicious order until we deem it a suspicious order.

If we would deem it a suspicious order, then that order would never be shipped and it would be reported to DEA and we would continue our investigation. And at that point any -- any controlled -- any of that drug, that particular drug family would be blocked in our system and -- and that

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pharmacy could not get any of that until we complete our investigation.

Most times, as I said before, if we have determined that an order is suspicious and we report it to DEA and we conclude our investigation, it usually ends up we block all controls to that customer and then we also report that to DEA.

Q. I'm -- I'm glad you mentioned that last part, that's a question that I had was if a pharmacy ordered an excessive amount of a particular family, like oxycodone, and that was denied because it was caught by the system, could they then also -- or in the alternative order hydrocodone, a different family? And I think your testimony is you would not ship the hydrocodone because it is also a controlled?

A. That's not what I said.

Q. Okay.

A. We hold the order, say if it's oxy -- it's oxycodone, let's just use that for an example, if -- if -- if that was held in our system, we would not ship that -- that order or any other subsequent orders of oxycodone.

Q. Okay.

A. And if our investigation took a day or it

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took a month, they're not -- they would not be able to order oxycodone.

If we -- if we determined that that order was suspicious and we reported it to DEA, we would continue our investigation into that pharmacy.

During that investigation they would not be able to get any more oxycodone but they could possibly get other controlled substances while -- while our investigation -- while we are conducting our investigation.

Most of the time, and I'm not going to use absolutes, but most of the time the investigation would -- would end where we would block all controls to that customer.

If we had ended up having reason -- reasonable suspicion that there may be diversion taking place and then we would report that fact to DEA and any state boards of pharmacy that we could.

Q. Were there communications between H.D. Smith and the pharmacy customers that were being investigated about the status of the investigation?

In other words, I'll -- I'll give you a more definite example, a pharmacy orders oxycodone, it is denied oxycodone because it's a -- it is an

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excessive order, is there anyone from H.D. Smith that calls that pharmacy and says, You know, we are almost done with your investigation, we hope to be able to release your order next week?

A. No.

Q. Is there anyone from H.D. Smith that calls that customer, from any aspect of H.D. Smith, and says, Sorry, you hit the threshold on oxycodone, you should try ordering hydrocodone?

A. No.

Q. That's never happened?

A. No, not to my knowledge.

Q. Do you know if salespeople would have had such a conversation?

A. I -- I cannot say that for sure.

Q. Do you know the extent of communications that the sales staff has with pharmacies when they are subject to investigations for hitting their thresholds?

A. They have communication with them because we allow them to communicate what we are doing with their account. You know, they'll communicate to the pharmacy that, Hey, you are blocked from oxycodone and we need to get a dispensing report and we are going to

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schedule -- you know, it could be -- it depends. Our -- you know, there's different phases of our investigation.

If we were going to do a site visit, the sales rep would be the -- the person that would communicate that and say that, you know, our compliance staff is going to come out and do a -- a site visit with you and schedule that because we don't -- we don't want to do -- we are not going to fly across the country and the pharmacy owner or pick is not there. We want the people that are decision makers to be there so we can discuss the concerns we have.

Q. Has H.D. Smith ever considered that the salesperson might be in a conflict with the compliance function in the example that you just discussed?

MR. PADGETT: Object to form.

BY MR. YOUNG:

Q. In other words, the salesperson is motivated to have the sale go through and the compliance person is motivated to make sure that the wrong type of sale does not go through and those two things are in conflict with each other?

A. The sales rep's main job is to sell, but

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we want to sell to good customers, good, compliant, legitimate customers. You know, they have no say-so in compliance decisions.

Q. Okay.

A. All we are using them for is a conduit for the discussion.

Q. I want to show you Euson Deposition Exhibit 17, which is essentially a collection of documents. It's -- it's two e-mails, a printout and -- a printout of, like, a ledger and then a printout of a spreadsheet, I think. I'll give you a minute to look at that.

A. I can hardly read that.

Q. You can't read it? I had -- we can -- I had that same problem. We can only copy what we receive.

Is that better?

A. Yeah. The focus is -- that -- that's fine. It's the copy, I think.

Q. Are you able to read that?

A. I -- I can read it.

Q. Okay.

A. It will just take me a second.

Q. Sure.

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A. Do you want me to read further? I can see that.
Q. Oh, no. Just familiarize yourself with the first page. We'll just focus on that first and then we can talk about the rest of it.
Have you seen this document before?
A. I don't recall. It was just -- I'm sure I have, but I don't recall seeing it lately.
Q. So this purports to be an e-mail from Brandon Sail -- Salyer?
A. Salyer.
Q. Salyer. You're familiar with Brandon?
A. Yes.
Q. Is he still with the company?
A. No.
Q. And, I mean, obviously the document speaks for itself, but -- but Brandon is a sales representative in the -- in the Louisville distribution center, is that right?
A. Yes, he was.
Q. And this is to P.J. Little who I think you testified earlier was your colleague in the compliance division?
A. Right.

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Q. And can you read for us, it is a big ask, I know, I'm sorry, the highlighted portions of this e-mail?
A. "This is a big LTC account," which is long-term care. "This account will purchase more than $3 million a month in Rx between Amerisource and H.D. Smith combined."
Is that -- is that it?
Q. And then it says --
A. I can't tell what --
Q. Yeah, I know.
A. -- what's highlighted and what isn't there.
Q. Yeah.
A. Is that it or do you need more?
Q. So then the next highlighted portion which begins with: "I don't want to rock the ship too much."
A. "I don't want to rock the ship too much. This is why we need to bump up their limits on the benzodiazepines, hydrocodone, oxycodone families, they would potentially give us much more business."
Q. Okay. And then if you could just read the response from P.J.? Or I'm sorry. It is actually a

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forwarding that P.J. sent to you.
A. From Lori Kirbach?
Q. Yes. Well, it is to Lori, I think cc'd to you. I can't -- it is difficult to make out, but what she says there?
A. "I would like to go ahead and raise their URLs for the families listed below."
Q. And there is some handwritten notations on this document. I don't know if these are P.J.'s or Lori's or yours.
Do you -- do you have any recollection as to who may have written these amounts?
A. That's not my writing. Maybe P.J.'s.
Q. Okay. And can you tell us what the amounts of the increase recommended by P.J. were?
A. Benzo six times, hydro 15 times.
Q. And the date of this e-mail was before or after implementation of the CSOMP?
A. After.
Q. Okay. Turning to the next page of this collection, this is -- purports to be an e-mail from Brandon -- I'm sorry -- from P.J. to Brandon.
Can you read -- I'm not sure if you can or not, it is very difficult to read, but are you able to

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make that out?
A. "I reviewed this account for an increase of their URL in the benzo, hydro and oxy families. I have increased all of these families to accommodate purchases. Per our discussion please provide written documentation regarding information about this account as a backup for justification of our changes. Please include the information about their switching wholesaler on a couple of different occasions and what our role has been. Please let me know if you have questions."
Q. Okay.
A. I'm not sure what order those e-mails were in.
Q. Yep, and there -- I believe --
MR. PADGETT: Is there a date?
MR. YOUNG: Yes, I believe it is cut off. These were produced by you all.
BY THE WITNESS:
A. It sounds like the first e-mail --
BY MR. YOUNG:
Q. Yeah.
A. -- was the history she was asking for.
Q. So the next page is a printout on

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H.D. Smith letterhead. Do you -- do you recognize this type of -- and it is obviously just an excerpt from -- from some printout, but do you recognize this type of document?

A. Yes. We called this our comment sheet.

Q. Okay.

A. It is basically a -- a chronological record of any changes that we would have made with different accounts.

Q. And what is the date of this entry?

A. April 22nd, 2009.

Q. And LAK, does that signify Lori Kirbach?

A. Yes.

Q. All right. And what does Lori say in the Note section?

A. "Increased URL for benzo and hydro after P.J. discussed with Brandon Salyer, the sales rep."

Q. Okay. So, and this is an example of the sort of communication between Brandon from sales and P.J. from compliance, and the result from this note is an increase in the URL or threshold for this particular customer.

Is this typical or atypical, or uncommon?

A. It's not uncommon.

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Q. Okay. Do you know whether or not Med Associates was investigated prior to this, this collection of documents here, Exhibit 17, investigated for exceeding its thresholds, ordering in excess of its thresholds?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. I can't say without seeing the documentation on it.

BY MR. YOUNG:

Q. But there would be some data that would -- or some report or due diligence file or something that would reflect whether or not Med Associates had been investigated?

A. We'd have a due diligence file on Med Associates.

Q. Okay. If -- assume for a second that Med Associates entered an order that exceeded its threshold for these three drug families, benzos, oxycodone and hydrocodone, this is an instance where sales is requesting of compliance to release or increase the -- the URLs or thresholds.

Is that accurate?

A. I regard this more of a -- a heads up from

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sales to give us information about -- more information about the customer and the situation therein with their other wholesalers.

You know, I don't have any problem with -- with sales giving us information on their customers. It helps us to know the customers more. You know, it doesn't necessarily mean we are going to do as they ask. We are going to do our due diligence before we would act on anything that would be requested like that.

Q. And as far as the reports or records of H.D. Smith that would serve as evidence of these examples, other than the due diligence files, is there some type of report or repository or database that we could look to to find instances where sales reached out to compliance and compliance increased URLs?

A. It was communication through e-mails.

Q. It would all be e-mail, okay.

Do you know if Med Associates was -- is still a customer of H.D. Smith?

A. With just the name and an account number, I'd need more information.

Q. Sure. I just figured it was worth a shot, if they were on your radar or not.

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On the first page of this -- this exhibit, the highlighted portion, there were the handwritten notes that says benzo six times and hydro 16 times.

Is that a typical type of increase of a -- a URL or a threshold?

MR. PADGETT: Object to form.

Go ahead.

BY THE WITNESS:

A. Well, at -- as I talked before, when we first developed the system, it was -- we had three times multipliers and then we were able to put multipliers -- we couldn't put a number. We had to put a multiplier. That was all our system gave us.

So -- but based on the -- the size of this account, I would -- without more information and knowing exactly what they were ordering and what the UR -- URLs are unit reportable level. Without knowing what the URL was to begin with for this family and where this customer fit in that family, I can't give you a good answer. All I can speculate is that with the size of this customer they -- these -- these increases are probably not out of the ordinary.

Q. When you say the size of the customer, do you mean the amount that they are purchasing on a

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monthly basis or do you mean, like, the --
A. We had -- we -- we -- as I said before, we have our -- we had our customers in revenue classes based on the size of the customer and what we found was that many times the bigger the customer, the less controls they actually bought, because it could include hospital customers that maybe have a very low percentage of controlleds.
So the -- the -- the three times multiplier may not be that high to begin with. I -- I don't know without all of the information to look at to give you an educated comment.
Q. Do you know if -- and this is an example that this Med Associates exhibit that we've -- we've had you talk about, do you know whether or not due diligence is completed on a customer before increasing its URL in controlleds like this?
A. Yes.
Q. Was due diligence done on Med Associates, to your knowledge?
A. Without further information, I can't tell you, but our practice is we would do due diligence before we raise any limits.
Q. Okay. So this -- it -- it would be

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unusual for an e-mail from sales to trigger an increase in URL without due diligence being done?
A. Yes.
Q. The reference in the last part of the e-mail where I believe P.J. was asking Brandon for documentation to support, if -- if that documentation came in after the URL was raised, what's -- what's the point of it?
Is it just a -- a recordkeeping requirement?
A. I -- I don't know all of the -- all of the particulars. There could have been a phone call that precipitated this. You know, any time that we, you know, had a discussion on a phone, we would want to memorialize that discussion in an e-mail. So without knowing all of the facts, I can't -- I can't tell you.
Q. Okay. That's fair enough.
I want to switch to Euson Deposition Exhibit 19, which is actually a letter from you, October 22nd, 2007, to Kyle Wright. I'll give you a minute to take a look at it.
A. I'm familiar with it.
Q. Okay.
You wrote this letter after meeting with

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the DEA and HDMA, is that correct?
A. Not HDMA. This was the meeting we had with Kyle Wright and Mike Mapes at DEA headquarters in October --
Q. Okay.
A. -- 2007.
Q. Did you attend a HDMA meeting on October 16th and 17th of 2007?
A. I -- I don't know.
Q. Okay. Let me -- let me go back one -- one exhibit to Exhibit 18. I will show you what is labeled a Draft Summary of HDMA DEA Meeting October 16 and 17. See if that refreshes your recollection.
And I'd -- I'd specifically direct your attention to the last page of this exhibit, that lists the attendees, under "HDMA Members in Person" you are the third name.
A. Then I guess I was.
Q. Okay. Fair enough.
So you attended this meeting of the HDMA and DEA. You -- you don't recall the meeting specifically?
A. Not specifically.
Q. Okay.

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A. I do remember a meeting with Kyle Wright there, so it may have been this one.
Q. And subsequent to this, I'll just refer back to Exhibit 19, which is the -- your letter to Kyle Wright, so you sent Kyle Wright a piece of correspondence, a letter, and it begins with: "Thank you for taking the time to meet with Larry Mackey, Brian Landry and me at DEA headquarters" and you are following up on issues.
There is a -- a highlighted portion on this first page. Can you just read that sentence for us?
A. "In addition, our division management will be instructed to review any orders they deem suspicious and stop shipment until investigated."
Q. And I -- you know, I -- I can't tell from that sentence, in contrast to your prior testimony, was that the practice prior to sending this letter or was this a new development?
A. Rephrase that.
Q. Prior to writing this letter or prior to meeting with Kyle Wright, was division management instructed to review any order they deem suspicious and stop shipment until investigated?

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A. Well, as we've discussed before, the -- the practice was to look at orders at the end of the month. This was in the transition phase of -- of, you know, when we are going from the manual system to the automated system and it was just a reminder to our division management that, you know, that we are developing this system and that this is -- you know, that -- that basically that's going to be the practice going forward.

Q. Did -- did Kyle Wright tell you during your meetings with him that the way you were doing things prior to CSOMP were insufficient?

A. Not that I recall.

Q. So what was the impetus to make the change?

A. As I said, we were already exploring an automated system in 2006 and 2007 to improve our processes and when we met with DEA in October, they asked us if we would put an automated system together. And I told them that we had been exploring it but that we would make it our priority to put an automated system together and -- and put it in practice by spring of 2008.

Q. Okay. You also in this letter describe

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new customer due diligence forms and I think you previously talked about this in answering another question.

But who developed these forms, was it -- was it just you or was there a committee of people?

A. It -- it was just me but it was with reference to other materials, materials that DEA had given me, materials that I had garnered from HDMA. So, you know, all of the wholesalers questionnaires were a little bit different, but basically on the same theme.

Q. You say in this letter that you are going to send these examples of the new forms to Kyle for a review.

Does -- was it your expectation that he was going to comment or edit these forms for you?

A. No. Historically in communications with DEA they give little to no guidance and it had been my practice to, when I had discussed something with DEA, whether it was a diversion investigator, Kyle Wright, I would then put an e-mail together, send it to them saying, This is what I understand our discussion was. Usually I'd hear nothing, and to me nothing was good.

There was a practice at one time about

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sending letters to DEA saying this is what you are going to -- this is what we are going to do and if you don't hear -- and if we don't hear different we consider that a yes. So that was the premise that I operated under.

So when I sent these -- these forms to them to take a look at, the same way when I informed them along the way on how we were developing our system, my expectation is if he had an issue with something, he would bring it to my attention, not that he was going to endorse what we were doing, but if there was something that we either misunderstood or there was something we were doing wrong, my expectation is that he would let us know that, Hey, that's not right.

Q. Okay. You close your letter with a commitment to implement all reasonable controls to prevent diversion of controlled substances for illicit use.

Did you have something specific in mind when you -- when you referred to implementing all reasonable controls? Or are you just talking about CSOMP or something more than that?

A. No. Just our -- our everyday commitment

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to -- to, you know, implement controls to -- to -- against diversion, not only CSOMP.

Q. Did you ever hear back from Kyle about the customer due diligence forms? Do you know, did he ever, like, say, Hey, good job or --

A. I don't think so, no.

Q. Okay.

Okay. Let's see. You -- I'm going to turn to Euson Deposition Exhibit 23, which is an e-mail, handwritten like a journal entry and, of course, a redacted handwritten entry, I'm hoping that maybe you'll be able to read. It is also pretty difficult to -- to read.

Once you are ready to talk about that, let me know.

A. Is there something redacted out of that e-mail after "order" and the -- it is a little hard to follow.

Q. Which one? After "order" there is, like, a space and a period?

A. Yeah, and then it goes into a monitoring program. I guess we don't know what that says.

Q. Yeah, I don't know. This is how we received it, so.

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A. Okay.
Q. So this e-mail is from you dated July 9th, 2007, to Scott Garriott. I think you -- you previously testified that Scott was a DEA employee, right?
A. Diversion investigator in Springfield, Illinois.
Q. And what was your purpose in sending this e-mail to Scott?
A. Can I finish reading it?
Q. Sure.
A. My purpose was just to let him know that we were working on a -- on an automated system. It did not go as scheduled in this e-mail. We had -- we had issues in the initial development of the system to make it work the way we wanted it to work. So that -- that highlighted area "beginning Ju-" -- "July 1" never occurred.
Q. So I -- I -- I don't want to testify for you, but I take it from this e-mail that that section is actually part of what Amerisource sent in its e-mail.
Is -- is that your recollection as well? Because your e-mail begins with: "This is a

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communication that Amerisource sent out to their customers. We are close to implementing our system but may need to tweak it based on the below."
And that's what I wanted to understand was whether "all of the below" was the Amerisource content? I think that -- and that may also explain the cutting and pasting or the redaction you were asking about.
MR. YINGLING: Objection to form.
BY THE WITNESS:
A. Yeah, I'm speculating that it is.
BY MR. YOUNG:
Q. Okay.
A. Based on the corporate security and regulatory affairs stuff.
Q. What was it about your CSOMP system that you needed to tweak based on this Amerisource notice it sent its customers?
A. I think I told you we originally -- when we originally started ours we were trying to do it by NDC and it was -- it was -- it did not give us the desired results that we needed to identify orders. So we -- we needed to tweak the system, and that's something we were working on. And then when -- in --

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later in 2007 when we got a -- a general concept of -- of Amerisource's system, that's what we tried to mirror.
Q. Okay. There is some handwritten notes on the bottom of this e-mail. It says: "Verbal response: Format is not required but Smith should give it serious consideration."
Do you know whose handwriting that is?
A. I don't.
Q. I'm going to turn to Page 2 and ask if you can identify, is that your handwriting?
A. No.
Q. Do you recognize that handwriting? Would you -- have you seen this document before or that entry?
A. I do not know whose handwriting that is.
Q. Okay.
A. I can only make an assumption that it might be Garriott's.
Q. Okay. I'm not sure how we obtained it from you all.
Okay. That -- that's all from that exhibit.
I want to turn to -- and I'm going to give

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you this one, it's -- because it's got the flags on it.
MS. COOK: Okay.
MR. YOUNG: And you look -- we'll give them that one, that version.
BY MR. YOUNG:
Q. Turn to Exhibit 24. Just take a look at that.
Is Exhibit 24 something that you authored?
A. Yes.
Q. What was the purpose of authoring that document?
A. The purpose was to outline what we were doing with our order monitoring program. This would have been sent, I don't know exactly who it was sent to, but I would have sent it to the divisions to disseminate. It was also -- went to Kyle Wright, I believe, to give him a -- an overview of -- of what our system was going to look like. I mean, I had had, you know, consistent, you know, constant communication with him in -- over the phone, but this was in writing, kind of what -- what we were planning on doing and how we were going to roll it out.
Q. Do you know the date that this was

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completed? It's -- it's not dated.
A. I think it was attached to an e-mail in March.
Q. Okay. Around the time that --
A. Of '08, I believe. I don't know the exact date.
Q. And you mentioned that you're not sure who all it went to, but do you recall whether this went to senior management people above you?
A. It would have.
Q. Does this accurately depict the background of DEA oversight of drug distributors?
MR. PADGETT: Object to form.
MR. YOUNG: That was a poor question, but...
BY THE WITNESS:
A. It would -- it would depict my --
BY MR. YOUNG:
Q. Interpretation?
A. -- opinion -- interpretation.
Q. So, I think it's 4 --
MR. PADGETT: You should have been a lawyer.
THE WITNESS: Before we get into that --
MR. YOUNG: Yeah.
THE WITNESS: -- can we take a break?

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MR. YOUNG: Oh, sure, by all means. Any time you feel the urge, let us know.
MR. PADGETT: It is almost an hour 15.
MR. YOUNG: Can we go off the record.
THE VIDEOGRAPHER: We are off the record at 2:25 p.m.
(WHEREUPON, a recess was had from 2:25 to 2:31 p.m.)
THE VIDEOGRAPHER: We are back on the record at 2:31 p.m.
BY MR. YOUNG:
Q. When we left off and took a break, we were talking about the brief overview that you had drafted. You've today looked at it a little bit, but you are the author of it.
Is -- is there anything in the brief overview that you recall that was a mistake or an error that you would change today, in other words, does it accurately reflect the brief overview of the CSOMP system?
A. I'd have to go into every detail of this to -- to determine that, but I authored this at the time.
Q. Okay. That's -- that's a better way of

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going about it, frankly.
There is reference made in this document and other documents, and I think your testimony today included this phrase "know your customer."
Do you know the origin of the "know your customer" phrase?
A. I'm not exactly sure. I think it is in the Chemical Handlers book.
Q. But --
A. There may be other reference to it. It's kind of a, I don't know, it's -- it's a -- it is -- it is something that's kind of the industry DEA expects you to know your customer.
Q. You mentioned that the original system, the CSOMP system had the three times multiplier which was off of a moving average of controlled purchases, right?
A. Yes, it would have -- it would have readjusted every month.
Q. So --
A. And it was also on a -- just to clarify, it was on a -- a rolling 30-day system, not a -- when we -- when we first rolled it out, not a calendar month.

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Q. Has H.D. Smith identified instances in which that aspect of the CSOMP system was manipulated by pharmacies?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Not that I'm aware of.
BY MR. YOUNG:
Q. Has H.D. Smith identified instances in which pharmacies used vulnerabilities in its CSOMP system to order more controlled substances than they should have?
MR. PADGETT: I'll object to form.
BY THE WITNESS:
A. What do you consider vulnerabilities in the system?
Q. Any type of vulnerability, have you as the head of compliance for H.D. Smith identified any instance in which a pharmacy has managed to navigate its way through your CSOMP system and ordered more controlleds than it should have?
A. If you are talking about manipulating our system, I don't -- I -- I can't think of an instance where they manipulated our system. Did pharmacies order more than their threshold allowed, yes.

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Q. And in such an instance did they receive such an order?
A. It would depend on the order.
Q. Is H.D. Smith aware of instances in which a pharmacy ordered and received more controlled substances than it should have been allowed to?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. You'd have to define that.
BY MR. YOUNG:
Q. Is H.D. Smith aware of instances in which any pharmacy in the country received an order of controlled substances that should -- it should not have shipped?
A. If we identified orders that were suspicious, we would not have shipped them.
Q. And I want to clarify. This is for the duration of H.D. Smith including before your tenure whether or not any customer received an order from H.D. Smith that should not have shipped?
MR. PADGETT: Objection; form, scope.
BY THE WITNESS:
A. You'd have to identify the order and -- and give me more -- more details on that order.

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BY MR. YOUNG:
Q. But you as the chief of compliance have not identified any such order?
A. No.
Q. I'm going to show you Exhibit 25. We won't spend a lot of time on it. It's --
A. Are we done with that?
Q. Oh, yeah, we are done with that one.
That is the -- let me take that one back. That's my copy.
Exhibit 25 is the procedures that were related to the CSOMP. It wasn't clear from this document when this was implemented.
Do you -- do you recall when this CSOMP divisional procedures were implemented?
A. It has got a March 22nd date on it, so I'm assuming then.
Q. Yeah, that was my question was whether or not that date was the date of implementation or the --
A. I assume so.
Q. Okay.
Did you draft this?
A. Yes.
Q. Did you have any assistance from P.J. or

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anyone else in compliance?
A. I had assistance from P.J.
Q. Did anyone outside of H.D. Smith assist in the drafting of this procedures document?
A. Outside of H.D. Smith?
Q. Yes.
A. No.
Q. So you didn't consult with Amerisource or Kyle Wright at the DEA or some outside consultant?
A. No.
Q. Page 6, Section I.3, it talks about releasing suspended orders.
Is H.D. Smith today aware of any violations of this procedure since 2008, this release suspended order with optional quantity change?
A. Give me a second to read it.
Q. Sure.
A. And could you repeat the question then?
Q. Is H.D. Smith aware of any violation of this procedure at any point since implementation of the CSOMP?
A. No.
Q. There is a reference to a "fat fingered" order.

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How -- I -- I guess that's where a finger hits a different key than it's intended to hit, is that right?
A. It's -- it's kind of an industry lingo, I guess. Someone meant to order five and they ordered 55 or something.
Q. How typical is that?
A. It is not very typical.
Q. Okay.
A. It happens.
Q. If an order is suspended because it is hitting a URL, what's the most typical reason to release a suspended order of these four options?
A. Okay, first of all, I just want to clarify, these are -- we had two different procedures. This is divisional procedures.
Q. Okay.
A. This is what we have trained and allowed our divisions to do on releasing orders. And you have to be aware of the time period of being 2008.
Q. What's the relevance of 2008?
A. There are some of these things that we don't do anymore.
Q. Ah, okay. So let's talk about the

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evolution of this real quick.
What -- what aspects of this procedure does H.D. Smith no longer do?
A. Our -- our divisions don't release any orders anymore.
Q. So all release of orders is done by --
A. Compliance department.
Q. -- headquarters?
Oh, compliance department.
Was there a point in time where URLs or thresholds was increased by division employees?
A. Never. They don't have the ability to.
Q. And who has the ability to increase URLs?
A. Only compliance.
Q. Can --
A. Personnel.
Q. -- any senior person within the company outside of compliance, in other words, if the president of the company wanted to, for his friend who owns a pharmacy, could he -- does he have the authority in the system to increase --
A. There would be no capability for him to do it. There is only authorized users.
Q. Okay. And the current authorized users to

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do that are who?
A. Currently, I have one compliance coordinator that is still working at H.D. Smith. Her. Probably P.J.
Q. Is -- is that because of the acquisition --
A. Yes.
Q. -- by Amerisource?
A. Yes.
Q. Okay.
A. There has been -- there has been transitions into other roles.
Q. I should have asked. Prior to the acquisition by Amerisource, who had the authority to increase URLs at H.D. Smith?
A. It would have been P.J. VanDermeersch, she's the -- she would have been the compliance manager, she was over licensing but she had overreaching duties and responsibilities. It would have been Kyle Rieger, who was our compliance manager, and then Tyler Walsh, who would have been our compliance analyst, and Christina Wools, who is our compliance coordinator.
Q. That's quite a few people that you've

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described, which is different than when you first started with H.D. Smith.
Is that, that assemblage of people, is that the largest the compliance department has been or was it larger?
A. I still at the time had three compliance managers in the field. I had a licensing coordinator. I had a couple of people at Valley that reported to me. I think I might have -- there may have been ten or eleven total in the compliance department.
Q. Was there any point in time in which you asked for additional staff in compliance but were not given authority to hire additional staff?
A. No.
Q. During your tenure in the compliance department, is it your opinion that it was adequately staffed at all times?
A. I believe so.
Q. I'm going to show you what was marked as Exhibit 26. This, I -- I suspect is the policy that goes along with that procedure, but is that an accurate description?
A. This was a revised policy, and I noticed that it's -- it's a -- it was labeled 810-V which

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meant it was part of a -- a VAWD requirement, so we would have relabeled our -- our policies and -- and -- to be able to submit to VAWD for their accreditation process. So -- so they would have been updated and -- at the time.
Q. I have a tabbed page on there. If you could turn to that tabbed page. It's -- here, I'll show you.
MR. YOUNG: It's, for the rest of you without the tab, it's --
BY MR. YOUNG:
Q. What page is that?
A. Five. Is that it?
Q. Yes, that one. Page 5. It has largely got a black box but with a little bit of writing at the top.
I -- we obviously can't see what's in the box. It is a picture of a screen shot of your system, I take it, but it describes differentiated color coding for these entries, blue, yellow and red, and I specifically want to ask you about the yellow. It defines the yellow as shipped orders over given URL.
How typical would yellow orders be shipped orders over given URLs?

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A. I -- I can't give you a definitive answer. You know, our -- you know, our system was designed to -- to assist us in identifying potential suspicious orders but not everything -- things that hit our system weren't always defined as suspicious. There may be different reasons for them. And, you know, all orders are -- were held, all orders were investigated, and if we -- if we did not deem that order as suspicious, then we would ship it.

Q. That -- that's what I wanted to ask was whether -- the red designation here is a suspended order.

Could a suspended order once it is released turn to a yellow order or once it's red in the system, it's red?

A. Red was probably it was suspended and remained suspended while we finished our investigation on it to determine whether it was a suspicious order or was not a suspicious order. So that would have been one that would have been continually -- you know, it -- it could be suspended for a long time --

Q. If --

A. -- while we conduct our investigation.

Q. And if it was determined to not be

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suspicious, would it then be coded yellow?

A. I don't know.

Q. Okay. I was just curious about when we dig into the data how we would be able to identify those, but I'm not sure that's possible.

Okay. That's all for that exhibit.

The next exhibit is No. 27 which is a -- a thread, I guess, or a collection of e-mails. It is also somewhat small, hard to read. Apologies in advance.

A. This one is easier.

Q. Okay. So this is a thread, it includes you, the -- the -- the top entry is actually to you from Dan Howard. It designates Dan Howard as the manager of operations in Pompano Beach.

Is that still the case, is Dan with the company still?

A. He has transitioned to MWI, a division of AmerisourceBergen.

Q. Okay. So I want to just talk a little bit about this thread.

On Page 2 of this thread, Dan says, "I" -- "I just released 1200 for APEX and 2200 for dispensing."

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I understand out of context in a vacuum it is hard to understand what -- what he is talking about there, but if you go back through the thread you have a -- well, I'm sorry, I've got to go all of the way to the original. July 29th.

Okay. Let's -- let's start at the very back. And at the back is a CC to you at corporate, and this is from Lori Kirbach who is the compliance coordinator.

"Just wanted to let you know that APEX," and she gives the number, "has ordered 5400 dosage units of oxy today, and Ira's has ordered 9400 dosage units of oxy today. I will leave these orders held in CSOMP until tomorrow since they were placed today. George, do we want to cancel them or mark them suspicious?"

At this point in time, this was in 2010, the -- the automation aspect of the system, wouldn't it automatically identify these orders? This seems like a manual process by Lori.

A. It holds the orders for review.

Q. I see.

So the system identified them as held, Lori reviewed them, and she wants to know from you

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whether to cancel them or mark them suspicious, is that right?

A. That's what the e-mail says.

Q. Okay. So -- and I'm sorry. That was actually to Doug. You were cc'd on it.

And Doug responds: "Lori, The eight accounts below will have a new URL. We will manage that locally and ship them up to the URL below. If they order more than the daily URL we will ship the maximum and suspend the rest."

And then it has an image that we cannot see.

And then the ne- -- third -- or I guess the second page is the end result, which is Dan Howard saying, "I just released 1200 and 2200 for dispensing."

How is Dan Howard in operations able to release these orders?

And it may -- I should mention, this may be a function of us not having the complete e-mail on this subject. This is the only thread that we have. But we don't see in this thread compliance approving this.

A. Yeah, I -- and I don't know that I can

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answer the question because I -- without more context I don't know what Doug is saying as far as the eight accounts, so, or have a new URL. They don't have anything to do with setting URLs.

Q. Okay. So would it be -- this be an unusual situation?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. I -- I don't know. I don't know what this is. I would have to get more information around this.

BY MR. YOUNG:

Q. Would it be unusual for an operations manager to be able to release held orders?

A. They could have the ability, but it would either be under the -- the restrictions that we put on them that were in the previous policy or they may have con -- they may have been in contact with Lori or myself. I just don't recall, but they are not going to -- the divisions did not just release orders.

Q. Evidence of that would be found in the due diligence file for these customers?

A. It should be.

Q. Okay. The next one is Exhibit 28. This is -- again, is a little easier to read, a shorter

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e-mail. This is actually dated the same date that the CSOMP divisional policy was created.

And I guess it probably makes sense to start with the initial communication in the thread, the -- the actual original -- what's going on here -- the original message was not included here. I don't know that we have that. But the first message is from you to a collection of people, Bryce, Steve, P.J., regarding Keller Apothecary.

Can you read that part that begins with "I agree to some extent"? It is the bottom of the first page.

A. From me. "I agree to some extent, but we have to be careful not to coach customers so that they can circumvent the program. We have already raised this account significantly and they still exceed the parameters in place. I also agree that more scrutiny should be placed on the doctor. That would be partially the pharmacy's responsibility, as it is ours to scrutinize the pharmacy. As far as DEA involvement, forget it. They hold the sword over our head but offer little guidance. They will not become involved with our business decisions but can come back around, suspend our registration if we don't make good

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decisions. Based on what I know at this time, I will not be responsible for raising this account any more than we have. If we have to explain our actions to the DEA, how would we justify it?"

Q. Do you recall this particular thread?

A. I don't recall the thread, I recall the pharmacy.

Q. The pharmacy, okay. What -- what do you recall about Keller Apothecary?

A. It was in urban St. Louis and it was a -- a pharmacy that catered to a -- or not catered -- it -- it was below a -- a doctor, a doctor's clinic that specialized in pain management above the pharmacy and most of his patients had their prescriptions filled at that pharmacy. We have extensive due diligence files on this pharmacy.

Q. Did you ever end up ceasing doing business with this pharmacy?

A. We did.

Q. At what -- do you know at which point in time you ceased doing business with them? This is dated May of '08.

A. I don't know.

Q. But the due diligence files would reveal

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that?

A. Um-hum.

Q. So at the very top -- well -- well, first, there is a -- a response from Bryce to your e-mail where he says: "Can we suggest to the customer to call the DEA diversion for their questions?"

And I, you know, we are -- we are at a disadvantage because we don't have the original e-mail that they are referring to here, but your response to that suggestion is at the top. And it's -- can you read that for us? It begins with, "No I wouldn't."

A. Can I read the rest of this first?

Q. Sure.

A. Okay. What's your question?

Q. Okay. So can you just read your response to Bryce's suggestion to call -- have the customer call the DEA?

A. Start with "No I wouldn't"?

Q. Yes.

A. "No I wouldn't. The first thing the customer is going to tell DEA is that H.D. Smith told them to call DEA. And what is the customer going to ask them? We are mandated to develop a system to identify suspicious orders. We have done that and

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Keller's orders have been identified as suspicious. We have reported that to DEA. It is our business decision, not DEA's. Our URLs are based on averages within a revenue class of customer. When we started this, we made adjustments to Keller's URLs based on division recommendations. Right now Keller's URLs are: Four times for benzo, 12 times for hydromorphone, 16 times for methadone, 12 times for morphine, 12 times for oxycodone. Our normal URL is three times the average. How comfortable are you standing in front of DEA and justifying raising these levels even more? If you have strong evidence that we should do so, I'm willing to look into it. I would recommend we find out more about this business and more about the one doctor that is writing 80 percent of the scripts he is filling."

Okay.

Q. Okay. So I just want to unpack this a little bit. The URLs at the time of this writing for oxycodone that you wrote was 12 times for oxycodone.

Is that your recollection as well?

A. Yes.

Q. The normal URL was three times the average, but this particular pharmacy had 12 times the

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average.

Do you know why H.D. Smith increased the URLs here to 12 times?

A. Yeah. We -- this -- this pharmacy was, you know, had pain management patients, you know, from the doctor above the store. You know, we -- and I don't know when in -- in the time of this e-mail, but, you know, it would be in our due diligence file, but I visited this pharmacy several times. I actually had a discussion with the doctor trying to get a better idea of his business. You know, at the time the -- the doctor and his prescriptions appeared legitimate. The -- there was no suspicion of diversion and so we raised the limits to -- to accommodate the prescriptions that the pharmacy was filling.

Q. Do you recall the ratio of controlleds to non-controlleds for Keller's Apothecary at this time?

A. I don't recall, no.

Q. Would the due diligence files contain that information?

A. I would assume it would.

Q. And you mentioned at some point in time you decided to no longer do business with Keller's.

What was the difference between this point

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in time and when you ultimately ceased doing business with them, what was the -- the final straw?

A. I would have to review the file to -- to get the final -- why we made the final determination to cease doing business with them. I can't tell you right now. I -- I don't know.

Q. Is Keller's Apothecary a typical or usual example of a pharmacy that has a pain clinic in close proximity to it?

A. It can be.

Q. Is that one of the factors that H.D. Smith used in evaluating the URLs for pharmacies?

A. It is one of the factors. We use a totality of circumstances, but it is one of the factors that we'd look at.

Q. Were there any other factors that played into your decision to no longer do business with Keller's other than the controlleds? Let me rephrase that.

Did you ever consider the percentage of cash pay customers at Keller's Apothecary as one of the factors to continue doing business with it?

A. We do, and to the best of my knowledge they were fairly low cash pay. It was in an area with

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a lot of Medicaid patients.

Q. What are the other factors that you used to evaluate pharmacies like Keller's? You mentioned the ratio of controlleds to non-controlleds, the proximity, and I'm trying to think of the others that you mentioned, but can you recall the other factors?

A. We use a -- a number of factors to evaluate pharmacies, and they can be, you know, cash pay, you know, the cash percentage for controlled prescriptions, cash pay for particular family of -- of drugs. It can be percentage of controlleds that are purchased based on what you -- you know, dispensing reports, what's the overall, you know, dispensing, the -- the cash, we look at the doctors that -- that are writing the -- the -- the controlled prescriptions, we look at the top doctors, we see, you know, what their -- you know, have they had discipline, what their board -- you know, are they board certified in pain management and, you know, what is their specialty, does it make sense, you know, with what they are prescribing, is there a monotony of prescribing, are there combinations of drugs that -- that are dangerous combinations, are the quantities of prescriptions that are being issued too high, are the

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patients coming from far distances.
In this case the -- the doctor is upstairs, but other cases it may be the doctor might be 50 miles away in an urban area. Does it make sense? So we look at the totality of different circumstances.
Q. And that seems like a lot of information to compile for each of your pharmacy customers. So how often do you do that full profile of a pharmacy?
A. As needed. As someone, you know, maybe, you know, hits our order monitoring system, we read about something that, you know, a pharmacy may have been raided, there is a doctor that may have gotten in trouble. We keep a list of doctors, you know, that -- that are kind of a watch list, an internal watch list. If we find a pharmacy that's filling prescriptions for a -- a particular doctor, we discuss that with the pharmacy. So there is -- there is a -- a number of different factors that go into our -- our due diligence process.
Q. Do you share your information about pharmacies that you've identified as suspicious with your other distributor companies, with competitors?
A. With DEA.

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Q. Just with DEA. Do you know --
A. Any time that we block a -- a pharmacy from controls or we exit the company -- the pharmacy altogether based on compliance concerns or if we've identified doctors in our -- in our research, we notify DEA of that.
Q. When you take on a new customer, are you able to discern whether or not that customer was ordering too many controlleds from its prior distributor?
A. We don't have any way of knowing that.
Q. So if a pharmacy like Keller's is essentially terminated from its relationship with H.D. Smith and it wants to continue buying controlleds, it will turn to another distributor, is that accurate?
Is there any other way for them to --
MR. PADGETT: Object to form.
Go ahead.
BY MR. YOUNG:
Q. Is there any other way for a pharmacy like Keller's to obtain controlled substances other than through a distributor?
A. No.

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Q. So if distributors don't know when pharmacies are ordering too many controlleds from one distributor, how can they evaluate them as a new customer?
A. You have to --
MR. PADGETT: Object to form.
You can go ahead.
BY THE WITNESS:
A. You have to evaluate them --
BY MR. YOUNG:
Q. I'm sorry. Go ahead.
A. We -- we have a process in place to evaluate new customers and, you know, there are -- recently there are some tools available from DEA where we can identify how many distributors a pharmacy would have ordered controlled -- or opioids from in the last six months, but there is no numbers, we don't know identities. The information that is received from DEA is limited to nothing at best.
Q. Does HDMA have any type of information sharing between and among distributors about suspect or problem pharmacies?
A. No.
Q. And you've never had -- you in your role

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as a chief of compliance for H.D. Smith have never had communications with any other distributor about problem pharmacies?
A. Now that we've been acquired by AmerisourceBergen, we will share a list of customers that we have discontinued selling controlled substances to.
Q. With Amerisource?
A. Yes.
Q. But not with other distributors?
A. No.
Q. Do you think that's something that -- that distributors should be able to do?
A. I would welcome any additional cooperation from DEA with the distributors to assist us in this.
Q. All right. I'm going to turn to -- one moment. This is Euson Deposition Exhibit 30. I'll give you this one. That's fine. Let me give you this one.
This is titled "Customer Due Diligence and Suspicious Order Monitoring Programs, Corporate Security Procedures," and it is dated November 2008.
Are you familiar with this document?
A. I'm familiar with this. I did not author

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this. This was -- this was when I was not at the company.
Q. Do you know who authored this?
A. I do not know.
Q. Do you know who --
A. The director of compliance at the time was Robby Robinson. But I -- I don't know if this -- if he authored this or not.
Q. Okay. On Page 3 of this document, there is a -- it should be a highlighted portion on your copy.
Do you see that?
A. Yes.
Q. Can you read that for us?
A. "If an order meets or exceeds a threshold or otherwise characterized as an order of interest, the order is automatically blocked to stop the ordered product from being shipped. The order may be evaluated as suspicious and reported immediately to the DEA or it may be investigated and reported at the conclusion of the investigation if but only if it is determined to be suspicious."
Q. Is that consistent with your understanding of the policy prior to your departure from H.D. Smith

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around this time --
A. It would be consistent.
Q. -- or is this a new development?
A. It -- it would be relatively consistent.
Q. If it was determined that a particular pharmacy's controlled substance order was suspicious, would you hold all shipments of controlleds to that pharmacy under this policy or just the family of the suspicious order?
A. By practice we would -- we would block all subsequent orders in that family. There could be times when, depending on the totality of the circumstances, we could -- we could block the whole pharmacy -- the -- all of the controlleds to a pharmacy at that point. It really depends on our investigation.
Q. And I was just trying to figure out whether this policy changed the prior policy that was in place when you were there.
A. This part of the -- there -- this --
Q. Not just this part but the policy in total.
A. I'd have to read the whole thing.
Q. Okay. Let me direct your attention to

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what I think is the -- is there only two pages to this? Oh, I'm sorry. To the second page. Well, the page -- the page that is Bates stamped 129 on the bottom, HDS_Euson_1 -- 00129. It begins with: "Investigation of orders of interest."
A. Okay.
Q. So this describes a Level II investigation.
Are you familiar with Level II investigations? Or is this something that your replacement came up with?
A. Where do you see Level II?
Q. In the middle of the paragraph, it says: "In instances when a customer's order meets or exceeds a threshold, or is otherwise characterized as an order of interest on a continuous basis, a Level II investigation will be initiated."
A. I'm not exactly sure what he means there.
Q. Okay. When you returned to H.D. Smith, do you know whether this policy was still in place or had it been revised at that time?
A. I don't know without -- without reading through this whole thing. I -- I can't comment on that.

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Q. Have you ever conducted or overseen the conduction of a Level II investigation as contemplated by this policy?
A. Well, if it means -- are you referring to the bullet points below that, the initiation of script data from customer, is that what you are referring to?
Q. Yeah. So it describes: "In addition to investigative guidance, the following procedures are required," and then it gives a bullet list of, it looks like seven or eight things to do.
Do you recall performing these -- all of these things on an investigation of a pharmacy during your tenure as chief of compliance?
A. We will initiate script data, which would be dispensing data review and analysis. We do practitioner due diligence, we perform usage analysis, and we do document our findings, we do evaluate our business relationships with the customer. You know, these are -- I said our -- our -- our due diligence processes are always evolving, trying to improve upon them, so, yeah, do we do -- we still do those things.
Q. So in the due diligence files for the pharmacy customers, we would see evidence or indicia of this type of investigation being done for customers

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that met that criteria, the continuous violation or, I'm sorry, the continuous --
A. Can I see that --
Q. Yeah.
A. -- again?
Q. The -- "Where the customer's order meets or exceeds the threshold or is otherwise characterized as an order of interest on a continuous basis, this investigation is required."
And what I want to know is if we review the due diligence files of H.D. Smith to what extent we are going to see this type of Level II investigation?
A. Any time that -- that a -- an order is held in our system, we do some level of an investigation into the order. That can be from review of purchase data all of the way to requesting dispensing data, do an onsite review, doing background investigations on doctors. Those are the things that we do every day on our customers.
Q. Yeah. That wasn't my question. My question is: That policy that was in place in 2008 says that those seven or eight criteria are required in a Level II investigation and what I want to know is

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was that policy consistently adhered to during your tenure in the compliance department at H.D. Smith?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I can't answer that in -- in certainty.
BY MR. YOUNG:
Q. Okay.
A. When I came back in April 2009 after getting up to speed with policies and -- and procedures, we continued to improve our processes.
Q. Okay.
A. But all of these things that are on these bullet points are things that we do on a regular basis.
Q. But you may not do them -- do all of them in every investigation of a Level II?
A. It may not get to that. We may -- we may get -- our Level II investigation may be we -- we do a purchase review and decide that -- that this customer is not someone that we want to do business with. We may go through a -- a usage report, a -- a prescription analysis and determine factors that -- that would give us reasonably there may be some diversion and we would con -- that we would -- that

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would stop our investigation and we would cut the pharmacy off from controlleds and report them.
So there is -- there is -- there is a lot of different steps in our investigation and -- and we can stop our investigation at any time to make a determination.
Q. You mentioned utilization reports. The -- or -- or maybe dispensing -- I forget what you called them. Dispensing reports?
A. They are both.
Q. What's a -- describe for us, what is a drug utilization report?
A. There is different forms of those, but a -- a -- just a typical utilization report that you get from a pharmacy software package usually just shows what their top drugs that they dispense and we as a practice try to get all of their drugs, not just controls, because we want to see what their percentage is. It would list all of their drugs in -- in order of dispensing in a certain time period, how many dosage units, how many prescriptions. That's something that most pharmacies can give us in a -- in a relatively quick fashion recently. It depends on your time period you are talking again. If you go

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back ten years ago, they were very difficult to get from pharmacies.
Q. So in 2008 how would you obtain a -- a DUR?
A. We would ask the -- the pharmacy for a dispensing report and we could get that in a 500-page fax, we could get most -- you know, I won't characterize, but it was difficult for a typical pharmacist to work a computer and get the information that we needed.
We -- we now employ -- I mentioned that before because I worked for them -- Pro Compliance, we use them as a vendor. They get the -- the dispensing information for us from the pharmacy and put it in a usable form that we can easily analyze with our analysts to look at all of the factors that -- that I mentioned before in a -- in a snapshot where we can, you know, make -- make easier more educated decisions on pharmacies.
Q. Did H.D. Smith ever determine that a pharmacy was misrepresenting its drug utilization report? In other words, underreporting controlleds or over-reporting non-controlleds to decrease its ratio?
A. I -- it would depend on the individual

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circumstance because the way we look at data is different than the way a typical pharmacist or owner of a pharmacy looks at data. And, as I said before, most of them are not great with computers.

Q. You are not aware of a pharmacy trying to game a system by underreporting controlleds in its DUR?

A. Not on purpose.

Q. Have you had any communications -- you -- you worked for Pro Compliance briefly, right?

A. I did.

Q. Are you aware of Pro Compliance experiencing that deception from any of its pharmacies that it acquires DUR data from?

A. No, because the -- actually, two parts. Not that they would know about. They get the information from the source, from the software and then they bring it in raw and then they run it through an analytical program, but that is not to say that if a -- if a pharmacy was filling fraudulent scripts or counterfeit scripts, that -- that wouldn't be readily identified. There would be no way to know that.

Q. Okay.

I want to show you, this is Exhibit 33.

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And this may be something you referred to earlier. This is -- it looks like a PowerPoint. Take a look and see if that looks familiar to you?

A. It is familiar to me. I'm not sure if I was the one that presented this or not.

Q. Okay. Is that somewhat consistent with the compliance training PowerPoint you described earlier?

A. Yeah, it's some of the information that's -- that's usually in our --

Q. Okay. And turn to -- yours is flagged. Let's see. Go to Page 4. It says, "Recent DEA Actions. H.D. Smith response in Florida Division."

What is that referring to?

Do you recall?

A. In light of the oxycodone issues that were occurring in Florida, and specifically South Florida where we had a facility in Pompano Beach, we had been in contact -- you know, constant contact, actually, with -- with DEA personnel in Florida regarding the -- the issues of oxycodone. And in response to some discussions that I had with DEA, Chris Smith made a decision to halt all oxycodone sales into Florida until every single account of ours could be visited.

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And so that's what a lot of this pertains to.

Q. Okay. I want to understand a little bit about that decision.

H.D. Smith decided that it should discontinue oxycodone sales into Florida of its own accord?

A. Yes.

Q. Did the DEA have any influence over that decision?

A. No, only through discussions I had with DEA about the issues with -- with oxycodone and with us being in South Florida, which was kind of the epicenter of that issue, that was something that -- that Chris Smith decided that H.D. Smith should do and we did it on our own accord.

Q. Okay. I want to show you Euson Exhibit 35. I'm going to come back -- well, we don't need to come back to that one, but this is a letter, I believe, from you to Leonard Levin at the DEA dated April 27th, 2010.

So, do you recall this letter?

A. Yes. I'd have to reread it all --

Q. Sure.

A. -- if you want me to answer about it.

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Q. And we don't need to do that. I'm just going to address some -- some particular points.

But this references a meeting. And it says: "This follows our meeting on Friday, April 23rd," which would have been the prior week of the -- of this letter. And it says in the highlighted portion, can you read that for us: "However"?

A. "However, given the tone and rhetoric of your statements during Friday's meeting, we are also concerned that the company is at risk for regulatory action by the DEA if it does not reduce sales of certain drugs to some of its customers in Florida. Accordingly, this letter is to inform you that H.D. Smith will immediately reduce sales of oxycodone and other controlled substances, as appropriate, to the customers you identified during the meeting on Friday."

Q. Okay. So there was a meeting, I take it, between you and Mr. Levin on April 23rd, 2010.

Do you recall that?

A. Um-hum, yes.

Q. At that meeting, just based on your letter here, it appears that Mr. Levin identified for you and for H.D. Smith particular pharmacy customers that it

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was asking you to reduce sales of oxycodone to.
Is that correct?
A. We had a meeting called by DEA. Leonard Levin was in headquarters. Also Susan Langston, who at the time I think was the group supervisor in the Miami district, field office. And I think Gayle Lane who was a -- a division -- diversion investigator at the time had a meeting and it was -- it was -- there was a discussion about the issues with the oxycodone in -- in Florida. And, you know, they -- it was a -- it was a discussion about customers of ours and customers in general and -- and the oxycodone issues in general.
Q. The -- the sentence that you read before references tone and rhetoric of statements made at the meeting by the DEA.
Do you recall specifically either the tone or the rhetoric that the DEA had at that meeting?
A. It -- it wasn't threatening, but it was to the point.
Q. A decision was made after that meeting, which is what this letter is memorializing, to immediately reduce sales of oxycodone and other controlleds to the customers DEA identified.

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You mentioned previously that Chris Smith made a decision to no longer sell oxycodone in Florida at all.
Did the April 23rd meeting with the DEA have any influence on that decision?
A. Just they did identify a few accounts of ours that they had issues with and we needed to do more due diligence on. There were already accounts in Florida that we had been shutting down due to oxycodone sales. And then after that, not only through this letter with -- with -- with Leonard Levin, I was also in constant contact with Susan Langston in -- in the Miami field office and we had had discussions about the oxycodone issues in general, and it was sometime after this, it wasn't as a direct result of this meeting, but it was sometime after this that -- that Chris Smith decided that we were going to halt all sales of oxycodone until we could get into every single customer and do complete new due diligence on it, on every customer that we had in Florida.
Q. Do you recall whether or not the customers that the DEA identified at that April 23rd meeting which you subsequently reduced their oxycodone supply,

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do you recall whether or not H.D. Smith had conducted a Level II investigations of any of those customers?
A. At the time?
Q. Yes.
A. I -- I don't know.
Q. Do you recall in the aftermath of this meeting evaluating the specifically identified customers identified by the DEA?
A. I can only speculate that we did. I would have to check our due diligence files.
Q. Do you know if there was a particular report that would have been prepared or a memorandum that would have been prepared reflecting that evaluation of these specifically identified customers in Florida?
A. It would be in our due diligence files.
Q. Just the individual due diligence file of that customer but not a more general document?
A. I don't know about those specific pharmacies. When we -- when we decided to halt all sales of oxycodone in Florida, we had kept a -- kind of a running spreadsheet on what our due diligence efforts are because we had also brought in some outside consultants to do site visits. We were, you

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know, trying to get access to dispensing reports. You know, we were doing our own visits. So there was a lot of moving parts and so we tried to keep it organized with a -- with a spreadsheet and we had weekly meetings to discuss the accounts with the division and what -- what our actions were.
Q. Do you know whether or not -- or do you recall whether or not the DEA opined that your policies and procedures or systems to identify suspicious drug orders were insufficient at that meeting?
A. They did not, that I recall.
Q. Did they make particular feedback to you about your policies, procedures or systems to identify suspicious orders at that meeting?
A. Not that I recall.
Q. Can you read for me the sentence which immediately follows the highlighted portion that begins with: "In light of"?
A. Wait. Where are you at?
Q. The first highlighted portion, it sort of ends with "and will continue to review orders of other customers." The next sentence there, it is not highlighted, it says: "In light of the meeting on

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Friday."
A. "In light of the meeting on Friday, H.D. Smith will take and apply the DEA's fade" -- "feedback to the company's overall policies and procedures for identifying suspicious drug orders."
Q. So reading that, does that refresh your recollection about any feedback that the DEA may have given you at that meeting about your policies and procedures?
A. I don't recall, but I also -- they would not have -- they wouldn't even know what our policies and procedures were.
Q. Do you know if your policies and procedures and systems, including the CSOMP that were in place in April of 2010, identified any of the pharmacy customers which were named by the DEA at that April 23rd meeting as suspect or suspicious customers in terms of their controlled ordering? In other words, were they on your radar?
A. I don't know without looking at that.
Q. Okay. Can you read the -- the next sentence, which is: "We heard"?
A. "We heard and understood the DEA's concern Friday regarding prescribing issues in Florida."

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Q. And -- and you can go ahead and finish it?
A. "And we at H.D. Smith hope to work in collaboration with the DEA to help address the issues."
Q. That seems to be a larger reference than just the pharmacy customers the DEA identified prescribing issues in Florida.
Do you know whether or not those concerns are what informed Chris Smith's decision to no longer sell oxycodone in Florida?
A. I believe that what they were referencing was the issue with pain clinics, the proliferation of pain clinics in Florida. We never sold directly to pain clinics, but prescriptions that were written by those pain clinic doctors would have filtered out and been filled by some of our customers. So -- and the reason why we, you know, were insistent on looking at prescription data, so that we could identify doctors that may have questionable prescribing habits that would be filled at our pharmacies.
Q. You had access to the data to be able to identify the providers that were writing the prescriptions?
A. Sometimes we did, sometimes we didn't.

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We -- we could not go in to a pharmacy and look at prescriptions, that's a HIPAA violation.
Q. Would a DUR report contain the prescriber DEA number?
A. It depended. At this time -- it depends on the timing.
Q. In -- in 2010?
A. Sometimes a pharmacy could give us that information, sometimes it was not easy to discern the prescriptions or the combinations. We could get a list of doctors that they were filling for, but not the detail. Some pharmacies were able to give that to us, some only gave us utilization reports that didn't have any doctor information on it and we had to ask them and hope that they were telling us the truth because we didn't have access to those records.
Once we were a -- you know, able to get Pro Compliance reports, that does identify the doctor that prescribes by prescription and that de-identifies any of the HIPAA information so there is no HIPAA violations.
Q. Were these issues isolated in a particular geographic region of Florida or was it just endemic to Florida?

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A. Population centers. South Florida mainly, but over in Tampa, Orlando, Jacksonville.
MR. PADGETT: The big cities.
BY MR. YOUNG:
Q. Okay. One more thing on this one.
On Page 2, the second -- well, the first full paragraph, it begins with: "While H.D. Smith was developing and implementing."
Could you read those two sentences for us?
A. "While H.D. Smith was developing and implementing new and enhanced procedures for SOM," which would be suspicious order monitoring, "H.D. Smith provided detailed information to DEA about its SOM. The DEA even requested that H.D. Smith enter into a memorandum of understanding regarding the SOM."
Q. Did H.D. Smith ever enter into that memorandum un -- of understanding or MOU?
A. That would be subject to interpretation. We had a memorandum of -- of understanding as a result of our meeting in October of 2007 where DEA wanted us to report suspicious orders to headquarters as opposed to the field office as per regulation and then also wanted us to report daily sales of all controlled substances to DEA on a daily basis. So we complied

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with that. We signed the memorandum of understanding. We complied with all aspects of it and DEA never signed it and they lost it.

Q. Okay. But it was your intention to enter into MOUs?

A. Yes, operated under the what we thought we were supposed to do under the memorandum of understanding.

Q. Do you know, was that typical for the DEA to seek MOUs with distributors?

A. I don't know.

MR. PADGETT: Object to form.

BY MR. YOUNG:

Q. Was it discussed at any of the meetings that -- the larger meetings, not the individual meetings that you had with the DEA, this idea of entering MOUs?

A. I -- I don't know. I believe there are some other wholesalers that -- that do daily controlled sales to DEA, but I -- I -- I don't know that for sure.

Q. Okay. I'm going to show you what I think is 35. I may have just gone out of -- yeah, it is the previous one, that one.

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And, again, I have flagged this for you, one, two, three, four --

MR. YOUNG: For the rest of you, Page 5.

BY THE WITNESS:

A. The tab there, the green tab?

BY MR. YOUNG:

Q. Yeah. The little tab, that's what I should say, Page 5.

MR. PADGETT: Which exhibit?

MR. YOUNG: 35. Was it 34? No. 35, yeah.

MR. LEADER: No, it's not 35.

MR. PADGETT: You just had 35.

MR. YOUNG: Oh. Is it 36? No. And I did 34. My apologies. I got all out of sequence there.

BY THE WITNESS:

A. Do you want that back?

BY MR. YOUNG:

Q. No, no, that's the right one.

And I just want to talk, you know, just quickly. This -- this document looks like another PowerPoint. Is this something that you prepared, do you know? I mean, it has got your name on it, but...

A. It would have been me or Debbie Komoroski or in conjunction with a combination of both of us.

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Q. Okay. On Page 5 of that document, it says, "SOM" and then the highlighted portion that we've highlighted, it says: "Excessive orders will be stopped and not shipped!"

Is this some type of change or a new policy or is this just a statement that this is how it is? What -- what's the -- what's the basis for this statement?

A. It is not a new policy. I think it is just reiterating what we've -- what we've been doing since we started CSOMP and that we don't -- anything that -- you know, anything that flags our system, if we -- it is held and then if we determine it's suspicious, it is never shipped. At this point in 2012, you know, it -- those orders weren't shipped.

Q. Okay. Prior to this training, I think this is called a training, yeah, sales training, prior to this sales training rollout were excessive orders stopped and not shipped?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. As I stated, once -- once we had CSOMP up and running, any orders that would have hit our system, which would have included something that --

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that went over our threshold, if you want to consider that excessive, that is stopped and not shipped until we determine if it's suspicious or if it's not suspicious. This was for sales and operations training.

BY MR. YOUNG:

Q. Okay.

A. It was just a reiteration of what we were already doing.

Q. There is a -- a bullet point beneath there which says: "It is extremely important that we know our customers" and then there is a reference to promotion purchases.

What is that referring to?

A. Without further reference, I'm not exactly sure.

Q. Are you familiar with, like, a summer sales promotion program?

A. There was promotions that -- that the -- that the company would put on, you know, occasionally throughout the year.

Q. Was H.D. Smith concerned from a compliance standpoint that promotional purchases that exceed the URL would artificially inflate the URL based on your

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formula?
A. Early on in my tenure there we stopped any controlled substances being offered on promotion.
Q. Okay. So promotion purchases then wouldn't impact suspicious order monitoring?
A. No, because there were no controlled substances that were on promotion.
Q. Yet under the suspicious order monitoring slide of this training module it is specifically mentioned?
A. Again, it was probably just a reiteration of what we already had in place.
Q. Okay.
A. And that there were no promotion purchases or, you know, there were no promotional -- controlled substances were not included in any promotional-type sales events.
Q. And then finally, it talks about assistance of the sales team and ongoing communication.
Do you recall what kind of message you gave during this training about ongoing communication with pharmacies from the sales team for suspicious order monitoring purposes?

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A. I'm going to assume that it's -- it's -- it's an ongoing communication with the sales staff because as I said we used them as our -- to communicate with the -- the pharmacies. They had the -- the personal relationship with the pharmacies, so any time we needed additional information, whether it was dispensing information or we were going to do an onsite visit, we coordinated that with sales staff. Occasionally sales came with us so they could see what we were doing when we did our site -- our onsite visits, sometimes they didn't, but it was all -- any contact with the customers is coordinated through the sales rep that was responsible for that account.
Q. Did you ever utilize sales staff to conduct inspections of pharmacy customers? I say inspections. That may not be the right word. Investigations or site inspections?
A. Not per se. They were a part of our what I would consider our initial due diligence on a customer. If they had a prospect that they wanted to bring on as an H.D. Smith customer, they would be required to fill out the -- the customer profile along with all of the other paperwork they do and that customer profile was then required to be sent to us

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along with photos of the pharmacy.
So I wouldn't call it a site inspection. I would call it a -- an additional -- an initial "know your customer" due diligence.
Q. Beyond the initial assessment or evaluation of the customer, did compliance ever rely upon or ask sales staff to conduct compliance-related investigations or inspections of pharmacies?
A. We asked them, and, again, going back to the training, to be vigilant and notifying us or identifying -- you know, if they identified anything that -- that we had trained them, you know, to red flag indicators. If there was lines coming out a door or if they looked like there were drug sales going on in the parking lot, we -- we wanted them to report that back to us. It wasn't a -- a compliance duty, but it's a -- you know, part of what they were trained to do.
Q. Okay. I -- I have the memorandum of agreement that we talked about before and I want to share this with you for one lim- -- very limited purpose. This is Exhibit 36.
And is that the document that you recall, the unsigned MOU between H.D. Smith and the DEA?

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A. I believe this is.
Q. And really I just want to use this document to refresh your recollection about the timing of the implementation of the CSOMP program.
On the last page there is a reference to what I think are your divisions or distribution locations. It is called Exhibit 1. And it has dates next to them.
Is that -- well, let me ask you this way: What do these locations and dates represent to you?
A. Well, it is not all of our distribution centers, so I'm not exactly sure, but I -- if -- if I could compare this with our documents, I would assume that this is when we rolled out CSOMP to our -- these divisions, but there were -- there are more divisions, so I don't know.
Q. Sure.
But I guess at the time that this document was created, this was the -- the state of affairs?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I can only assume, because it's not a complete list, that this is the timeline that we reported to DEA that we would roll out our CSOMP

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system to the various divisions.
BY MR. YOUNG:
Q. Okay. Okay. Thank you.
We are getting there. Are you okay as far as -- everyone at the end?
A. I'm fine.
Q. Bladders are nice and dry.
This next document, which is Exhibit 37, it is a little lengthier, and let's give him that version. I want to use this one.
So this, again, may be a document that you have never seen, but that nonetheless has been provided to us, which is a report of investigation by the DEA.
Have you ever seen that document?
A. I think I've -- it -- I think this -- I've seen this in -- in connection with SafeScript cases.
Q. Okay. I want to direct your attention to Page 13 of this document regarding ARCOS reporting.
A. I think there were numbers somewhere. Oh.
MR. PADGETT: Page 13 of 24?
MR. YOUNG: I believe so. That's what my notes reflect.
MS. COOK: HDS_Euson_00165 -- 166.

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MR. YOUNG: Ah, there we are, yes.
MR. MARTINEZ: Bates No. 166.
BY MR. YOUNG:
Q. So I'm sorry. It's Page 14 of 24, and it's Section H, ARCOS Reporting. This report references errors in H.D. Smith's reporting of its ARCOS data to the DEA.
Are you familiar with that issue from 2006?
A. Yes.
Q. Do you recall the cause of the problem with the ARCOS reporting in 2006?
A. My understanding, it was something to do with an IT glitch in our system that had -- that was corrected, but that was -- I don't know all of the technical parts of it.
Q. Sure.
Are you familiar with any other glitches in ARCOS reporting from H.D. Smith to the DEA aside from the -- the one referenced here in 2006?
A. There is -- there is occasional errors in -- in reporting, and it can be a variety of different reasons for it. It could be, you know, an ND -- a new product that DEA doesn't have a record of

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in their NDC files and we report it and they send it back as an error. There is a -- it -- it's a -- we report monthly for all of our DCs and there is always -- I don't want to say always, but it is not uncommon to have errors in ARCOS reporting.
Q. But in your role as chief of compliance during your tenure, have you uncovered more than a one-off type ARCOS reporting problem?
A. No.
Q. So the data that the DEA has in its ARCOS database regarding H.D. Smith transactions would be accurate aside from a handful of errors you described?
A. I can't speak to the accuracy of DEA records.
Q. The -- the data that you reported to the DEA in the ARCOS data stream, upstream to the DEA, that would be accurate for the most part?
A. To the best of my knowledge.
Q. The -- this document also references, I think it's -- I'll find it in a sec -- oh, here it is. On Page 4 of this document, it references DEA reg -- oh, wait, I'm sorry. That's not correct. I'm looking for the section that has the 12 vendors that were no longer -- this right here.

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We'll find this reference in just a second, but the DEA notified H.D. Smith that 12 of its customers' DEA registration numbers were no longer valid.
Is that -- is that typical, obviously we are --
A. Can you show me where --
Q. Yeah, we will, but --
MS. COOK: HDS_EUSON_00167 on the top of the page.
MR. YOUNG: Page 15 of 24.
BY THE WITNESS:
A. Page what? I'm sorry.
BY MR. YOUNG:
Q. It's in the -- it's in the continuation of that ARCOS section, I believe. It is the last two sentences:
"H.D. Smith had also been notified by ARCOS of approximately 12 vendors and a few customers whose DEA registration were being used to report transactions were no longer valid. These problems are in violation of 21 CFR 1304.33."
Is that the only instance of this that you are aware of or is this fairly common that people lose

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their DEA registration numbers and they don't notify H.D. Smith and so you keep doing business with them?
A. I know what the issue with the vendors was. We had, and it was a rela- -- relatively new process of manufacturers using third-party logistics companies back in 2006. So if we had a manufacturer that we were purchasing from, at this point we had their DEA -- their DEA registration on file. We were purchasing from them. They, in turn, instead of shipping it from their DEA-registered site would ship, have it shipped from a third-party logistics company, which could be UPS.
Q. I see.
A. And it would come in from UPS, it would have an -- and according to regulation, you have to buy -- or you -- you have to reflect the DEA registration from who you received the product from. So it was inaccurate reflection of -- that we got the product from, say, UPS instead of from Mallinckrodt. I'm just -- I'm throwing those examples out. That was the issue with these.
Q. No, I understand.
A. And we did correct it and we made -- we made modifications to our paperwork that our

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purchasing department used to make sure that we knew where the product was coming from, if it wasn't coming from the -- the actual manufacturer's registered facility but it was coming from a third-party logistics or a contract manufacturer, there is a lot of different variables in there, but...
And the customers, I don't know the exact issue with that. We do now have a -- a daily feed of -- from a company called NTIS. They work with DEA. And those -- those numbers daily are bounced against our customer lists and if anyone -- if there is an issue, our system automatically stops any sales to that customer.
Q. When did that contract with NTIS begin?
A. We've had it for a while. I believe at one point it was a weekly feed and then they offered a daily feed and we went to the daily feed and I don't know if that's why there was a -- a issue with a few customers here. I'd -- I'd have to look into it further to -- to give you a better explanation.
Q. Okay. I'm going to turn to Exhibit 38. Exhibit 38, why don't you take a look. I think you authored this document.
Well, I'm sorry, you didn't author. This

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is actually to you.
A. Right.
Q. Are you familiar with this document?
A. Not particularly. I know it's addressed to me and I'm sure that I got it back in 2010. I know Andrew Burchard was a -- at the time we had an internal audit team.
Q. I direct your attention to the second page of the document. It talks about missing customer due diligence profiles and site visit limitations. And let's just kind of walk through these highlighted portions here. The first one is titled "Missing Customer Due Diligence Profiles."
Can you read that?
A. "None of Division 3 Smith Medical Partner profiles have been completed" -- "completed at this time."
Q. What is Division 3?
A. Smith Medical Partners was our specialty -- our specialty division that service mainly doctors' offices.
Q. And the next highlighted section says: "Profiles have not been completed for the Smartsource customers in the CA," I don't know if that's

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California division?
A. Yes.
Q. What is Smartsource customers?
A. Smartsource is a generic program run by H.D. Smith to increase sales of generics. And I'm not avoiding your question. I'm getting my head around it --
Q. Yeah.
A. -- Smartsource. It's a -- it's not a -- it's not a separate division. It's a program where they have -- market to -- to customers to increase generic sales.
Q. Did that include controlled substances like opioids?
A. They are not -- they do not sell C-IIs.
Q. Okay. So no Smartsource customers receive C-IIs?
A. And they weren't allowed to have -- we wouldn't sell them controlled substances unless we had profiles and vetted them out first.
Q. Okay.
A. So there may not have been profiles done on all of them, but they weren't buying controls.
Q. Without the profiles --

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A. Yes.
Q. -- they can't get controlleds?
Okay. So I want to skip down to the Site Visit Limitations section just below there.
It says -- are you -- go -- can you go ahead and read that paragraph for us?
A. "It was determined through testing that the customer site visit control is effective. However, with current resources the compliance team is unable to complete all needed site visits within the year. Current high risk customer population was estimated at 200, but is likely substantially larger than that. Only 37.5 percent of the current high risk customer population can be visited with current resources."
Q. Do you agree with that site visit limitation assessment from Mr. Burchard? "You" meaning H.D. Smith. I should clarify.
A. Yeah, I -- I understand.
MR. PADGETT: Object to the form.
BY THE WITNESS:
A. I don't -- without more context around this, I don't recall what he was talking about here and what he was considering high risk customers and

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how he estimated it at 200. I don't know what criteria he was using. He was an internal auditor with no compliance experience.
Q. How many site visits could the compliance team conduct within one year in the year 2010, as staffed in 2010?
A. I can't recall how many we had.
The only way I can answer that is that I -- that's a -- site visits were -- were performed as -- on an as-needed basis for customers that we determined that we needed to go visit to do additional due diligence on and we did those in a timely manner. You know, they were -- I -- I had people in California, I had people in Florida, I had people up in the northeast, myself in the Midwest. We've used outside sources at times to do due diligence. So we were adequately staffed --
Q. Okay. So --
A. -- in my opinion.
Q. -- do you disagree with the audit recommendation about additional staffing for completing customer profiles and visits?
A. That's a loaded question because I thought we were adequately staffed, but if this would provide

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me with more staffing, I'd take it.
Q. Okay. I think earlier I asked you whether you had ever requested and were denied more staffing and your answer was no, right?
A. No. We continually through my tenure increased our staff.
Q. At the time that this audit was done and the findings clearly were routed to you, you were identified on the document as management owner and it was addressed to you, there is an audit recommendation of additional staffing to conduct these site visits.
Do you recall whether or not any additional staffing was provided to you to achieve these site visits?
A. I would have to have the dates of engagement, but I know that, you know, our -- from 2010 our staffing did increase.
Q. Do you know whether or not the high risk customer population which in this report is estimated at 200, whether or not that customer population was visited within the year?
A. I would not know that without knowing who those customers are and I -- I don't know what his definition of the high risk customer base is.

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Q. If you received this recommendation about your department compliance that used the term "high risk customer population," would you inquire of the auditor what he means by that?
A. Without seeing my response, I don't know, but I'm assuming I would.
Q. You don't recall sitting here how you handled the receipt of this report?
A. No.
Q. You have not used the term "high risk" to refer to your pharmacy customers, that's not a phrase that compliance uses?
A. I -- I can't be certain that term has never been used.
Q. By you?
A. I may have.
Q. Is there another term of art or euphemism that you might use within the compliance department to refer to customers that someone else may refer to as high risk?
A. If someone referred a customer to me that they thought was high risk, it would be someone that we would do extensive due diligence, again --
Q. What is another --

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A. -- depending on who it was.
Q. What is another term that you would use to describe such a customer?
A. If I was to use the term "high risk," I would assume that they most likely would not be a customer of ours anymore. I just -- I can't tell you that that's a normal --
Q. Let me give you a better, more concrete example.
The Keller's Apothecary pharmacy that we talked about earlier, at some point you ended up investigating them and made a decision to no longer do business with them.
During the course of that investigation, how would you refer to Keller's Apothecary, what term would you use to describe them as a customer? Were they high risk?
A. I don't know if I used that term or not.
Q. How would you describe them?
A. You know, and -- and it depended on various times of our investigation of them and our -- our investigation around the -- the -- the primary prescriber, the pharmacy itself.
When we decided to stop doing business

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with a customer or blocked our controls, when we contacted DEA, we didn't use the term "high risk," we used -- we just said that due to our -- basically due to our compliance review, we were no longer going to con- -- provide this pharmacy with controlleds.
Q. So you can't recall a particular term of art or euphemism or descriptor for pharmacies like Keller's Apothecary?
A. I -- no, no.
Q. Okay.
Okay. Moving off of that document on to Exhibit 39 which is a two-page document actually from Mallinckrodt. And this is on Mallinckrodt letterhead and it is called "H.D. Smith SOM Audit" dated March 29th, 2012, in Hazelwood, Missouri.
Do you recall receiving this document?
A. I'm sure I did.
Q. Do you recall attending a meeting with Mallinckrodt about suspicious order monitoring?
A. I attended several meetings with Mallinckrodt to discuss accounts and controlled substances in general.
Q. Was that typical among your manufacturer vendors?

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A. No.
Q. And --
A. Now I'm thinking that Mallinckrodt instituted it. I don't know of -- I know -- I see this date, 2012. I don't know where in the process, if that was the beginning of when they instituted these meetings, but, you know, they reached out to us to meet with them and we met with them on a -- on a regular basis. We had conversations with them regularly.
Q. So there's two things I want to talk about on this document. The first is the second sort of paragraph or section that says: "H.D. Smith refuses to sell oxycodone to a pharmacy that does business with any 'pain doc' in Florida."
Is that referencing the Chris Smith policy that you discussed earlier or is this something different?
A. Can I read through this for a minute?
Q. Sure.
A. Yeah, this, I believe, is -- it's not our report. It's Mallinckrodt's. So when they say "refuses to sell oxycodone to a pharmacy that does business with any 'pain doc' in Florida," I don't know

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that that's an accurate statement, and I'm -- you know, that's -- that's their words.
Q. Okay. So you disagree with that statement that H.D. Smith refused to sell oxycodone to pharmacies that do business with pain docs in Flon -- Florida?
A. You know, part of our due diligence on pharmacies in Florida was to get, you know, to know them and to see who they were filling prescriptions for. You know, a typical pharmacy may do -- take -- fill prescriptions for 6-, 700 different physicians in a month's time. We would concentrate on the top prescribers. We usually found that five or six prescribers in a pharmacy, at most, were responsible for most of the controlled prescribing.
And we had a list of doctors that we used that were -- that we thought were pain management doctors with questionable prescribing habits and if we saw those doctors in dispensing information from our pharmacies in Florida, we would discuss that with the pharmacy. And if they continued to fill those prescriptions, we would not sell controlleds to those pharmacies, but to say that a blanket statement of any pain doctor in Florida, I can't say that.

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Q. Okay. Did you have an agreement, a written agreement with Mallinckrodt to share information with them?
A. Not through compliance and I'm not -- and I'm assuming that it's -- it's written, but there is some sales data that is transmitted to different manufacturers through wholesalers.
Q. Yeah, and I'm specifically referring to, like, a compliance issues?
A. No.
Q. No.
A. We just did this as we agreed to meet with them.
Q. Mallinckrodt approached you about meeting --
A. They did.
Q. -- about suspicious order monitoring?
A. About controls, not about suspicious order monitoring.
Q. Do you know the impetus, why Mallinckrodt decided to start doing that? Did they share that with you?
A. I do not know.
MR. MILLER: Hayden Miller on behalf of

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Mallinckrodt objecting to the form and scope.
BY MR. YOUNG:
Q. I'm sorry. I didn't hear your answer.
A. I do not know.
Q. Mallinckrodt in this document appears to -- they reviewed your policy, so you shared your corporate policies with them.
Do you recall doing that?
A. We may have.
Q. And then the -- the follow-ups, there's a bot- -- at the very bottom it says: "Requests follow-ups. H.D. Smith to provide dispensing data on tourist pharmacy to Mallinckrodt."
Is that a typical information exchange?
A. When we were doing due diligence, specifically after discussions with Mallinckrodt, we would share our due diligence with them on the pharmacies and if that included a dispensing report, we would -- we would provide that.
Q. This identifies a particular pharmacy.
Do you recall whether or not that was the only pharmacy that you shared with Mallinckrodt or was it broader than that?
A. I'd have to know the time period, but

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we -- we shared files with them.
Q. Okay.
A. From time to time.
Q. This also mentions a pharmacy, Deris Pharmacy, and the note on Deris Pharmacy, there is actually two, one says, "Reevaluate... Higher cash sales," but the Note 4 says: "Concerns. Pharmacy using four distributors. Mallinckrodt requesting due diligence from other distributors."
Do you recall with regard to Deris pharmacy whether or not you shared due diligence information with Mallinckrodt?
A. I do not know. I'd have to -- that would be in our due diligence files.
Q. Is it typical for a pharmacy customer to be served by four distributors at the same time?
A. It's typical for pharmacies to use multiple wholesalers and particularly in certain areas of the country.
Q. How about four, would four be typical or --
A. It can be. There is many -- especially in urban areas where pharmacies are, New York metro, L.A., it is typical for them to price shop.

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Q. Do you use drug utilization reports on pharmacies that have multiple distributors, is that like a -- if -- if the pharmacy has multiple distributors, then you do a drug utilization report or is there no connection between the two?
A. It would depend on the circumstances. Many times we wouldn't know that information.
Q. Okay. We'll shift gears to another document.
MR. PADGETT: Maybe a --
MR. YOUNG: Break?
MR. PADGETT: -- heading down the stretch break? We've been going a good --
MR. YOUNG: Do you guys want to take a break?
THE WITNESS: Sure.
MR. PADGETT: Yeah.
MR. YOUNG: Go off the record.
THE VIDEOGRAPHER: We are off the record at 4:13 p.m.
(WHEREUPON, a recess was had from 4:13 to 4:24 p.m.)
THE VIDEOGRAPHER: We are back on the record at 4:24 p.m.
BY MR. YOUNG:

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Q. Mr. Euson, do you recall your Texas facility, I'll call it H.D. Smith Texas division, receiving a -- a DEA, what do we call this, a Formal Notification of Deficiencies in 2014?
A. You'd have to show it to me.
Q. I -- I will certainly do so. I just wanted to see if you recall before I did. I'm handing you Exhibit 41, which is a letter to H.D. Smith from the DEA dated November 21, 2014.
A. I don't recall seeing this. This -- I wasn't at H.D. Smith at the time.
Q. Okay. When you returned to H.D. Smith most recently, is this something that you would have been made aware of or just it happened while you were gone and you would never learn of it?
A. I'd have to read through this to see exactly what it is detailing.
Q. If you're not familiar with the substance of this violation letter -- let me ask you: What did you do to prepare for today's deposition?
A. I went through --
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. Well, I'm concerned because this is a

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letter from the DEA indicating violations at a Texas facility and a representative from H.D. Smith needs to be here today to talk about CSOMP and its suspicious order monitoring violations and you're not familiar with this -- this incident in H.D. Smith's history.
And I want to understand is that because this was overlooked or because it happened while you were gone, did you fail to prepare for the -- this type of information? This document was provided to us by your counsel.
MR. PADGETT: Object to form.
You can answer.
BY THE WITNESS:
A. That wasn't my answer. My answer was, yeah, I'd have to -- I said I'd have to read through this to see what -- what the -- the violations are. I may have when I came back seen this, I may not have. I don't recall. But that doesn't mean that -- if I read through this, I may be able to answer some of your questions.
BY MR. YOUNG:
Q. Sure. Please take the time to read through it.
MR. PADGETT: In light of the -- kind of the

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statement you made, which topic are you aligning with this Exhibit 41?
MR. YOUNG: What do you mean which topic, which 30(b)(6)?
MR. PADGETT: Which 30(b)(6) topic that you are suggesting he wasn't adequately prepared for.
MR. YOUNG: Sure. Relating -- well, hold on a minute here.
MR. PADGETT: It doesn't really seem to fit under administrative actions.
MR. YOUNG: Your interact -- No. 7: "Your interaction with the DEA related to the scheduling of controlled substances."
MR. PADGETT: Scheduling, that's not even close.
MR. YOUNG: I'm just going through them one by one.
MR. PADGETT: There is nothing to prep on that.
MR. YOUNG: Hold on. I've got to go to the first one. While you are reading that.
MR. PADGETT: Sorry. I'm pretty anal about 30(b)(6) reps.
MR. YOUNG: Oh, we'll -- we'll present this tomorrow, too, sorry. Don't worry.
Where is my little guy. Here we go. I've

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got it.
The First Amended Notice, Letter H, Letter G, Letter A, Letter I, Letter J, specifically Letter M. That ought to do it.
BY MR. YOUNG:
Q. Are you familiar with the document?
A. I know what it is. I'm not familiar with it. I -- I may have seen it, I may not have.
Do you have any other information as far as like the -- the response that we would have written within 30 days?
Q. I'm really limited to what your counsel provides to me, so I'm not --
A. I mean, this -- I mean, this is not like a formal action. It's a -- you know, it's a notification, you have time to -- you have 30 days to address what they have noted in here, and I don't know just from this letter, like as with three, with -- with the order monitoring, you know, what -- what the reference is.
Q. Yeah, that's -- that's really what I wanted to -- to focus on was No. 3.
A. I don't know if there were specific details that they gave the division that -- that

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brought them to this conclusion. I -- I do not know that based on the information that -- that's here in this letter.

Q. So earlier in the very beginning of this deposition I asked you whether or not H.D. Smith had ever been in violation of the CSA requirements, and I believe your testimony was, no, it had not. Yet in No. 3 of this letter, the DEA says:

"The firm did not operate a system to disclose to the registrant suspicious orders of controlled substances in violation of 21 USC 827(d) and 1301.74(b)(2)."

So I understand your testimony today is you're not familiar with this and you don't have a background in understanding what happened in Texas, but in light of this letter and what I've just read to you, do you wish to change your testimony with regard to whether or not H.D. Smith has always been in compliance with the CSA?

A. No, because this -- this letter doesn't give us enough information to know where they are going with this. You have -- you have 30 days to respond. I don't recall that there was any official letter of admonition or anything else that would have

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gone with this. So I don't know if this was explained away, if it was, you know, satisfactory to DEA. There is not enough information to answer your question just based on this document.

Q. That's what I was hoping to obtain from your testimony today, but you're not familiar enough to give me testimony.

A. Well, not without knowing what the response was and getting more background into this.

Q. How about with regard to No. 1 of this letter:

"A controlled substance accountability audit revealed the firm did not maintain complete and accurate records of controlled substances distributed by the firm. This is a violation of 21 USC 827(a)(3) and 21 CFR 1304.21(a)."

Do you have any recollection as to whether or not H.D. Smith responded to this particular aspect of this Texas violation?

A. I'm assuming they did.

Q. Who would it have been at H.D. Smith that would have responded?

A. November 2014, I don't know.

Q. Would this type of letter be a big deal to

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H.D. Smith?

A. Yes.

Q. This is a pretty significant finding by the D -- DEA?

A. Any -- any time --

MR. PADGETT: Object to form.

BY THE WITNESS:

A. -- if you were to get any type of letter like this we would take it seriously, because we take our responsibility seriously.

BY MR. YOUNG:

Q. Do you recall during your tenure, so only the time when you were there, receiving a letter like this from the DEA?

A. Not particularly.

Q. When did you return to H.D. Smith?

A. During this time period?

Q. Yes, sir, after this letter.

A. May 31st, 2016.

Q. And you don't recall in 2016 or any point thereafter discussing issues out of the Fort Worth division relating to this DEA letter?

A. Not specifically, no.

Q. Who -- who held your position at the time

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of this letter, November 21, 2014?

A. There -- prior to my coming back a Tracey Hernandez was the vice president of compliance and security. I do not know her dates of -- of -- of employment. I know after I left in 2013, one of my compliance managers, Bill Stivers, assumed some of the duties that I was doing, but without further information regarding this, I can't answer that question as to who would have responded to this.

Q. Is this type of document something which would have triggered a review by attorneys for H.D. Smith, either internal or external?

MR. PADGETT: I'll object to form.

Go ahead.

BY THE WITNESS:

A. Again, without the proper context on these three items, I can't answer that. I don't know.

BY MR. YOUNG:

Q. If you received a letter like this when you were the chief of compliance, what would you do with it?

A. I would have investigated it. I would have gotten with the -- Tim Van Bakel who was the operations manager at that division and discussed what

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the findings were --
Q. Is Mr. Van Bakel --
A. -- and all of the situa- -- you know, the situation surrounding it.
Q. Is he still with the company?
A. He is.
Q. Do you know whether or not he is still in charge of the Texas division?
A. He is. They have since moved.
Q. If you received a letter like this, would you refer this or forward it to inside or -- or outside counsel for the company?
A. Again, it would have -- it would have depended on the circumstances surrounding this and if there was explanations or remedies, it -- it -- it would all depend.
Q. I want to show you -- I'm going to move off of this document. You don't have any particular knowledge about it.
MR. YOUNG: I may want to revisit this document. I think we are going to reserve our rights to revisit this particular topic. It may be isolated to Texas. I don't know. But obviously we want to talk about the violations in Texas and what was done with them and

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the witness isn't prepared today to talk about that. So we are going to reserve our rights to revisit that particular issue.
MR. PADGETT: I'm going to object to the assumption of violations -- the allegations of violations.
BY MR. YOUNG:
Q. Okay. So, I want to show you now Exhibit 42-ish. Yes, Exhibit 42, if you will.
And that one is particularly small. I apologize. You might be better served looking at the screen, although I'm not even sure that's a very good copy.
Have you ever seen this document before? I think this is dated while you are not with the company, so that's why I ask.
A. I may have seen this one when I came back.
Q. Okay. This is called Project Initiation Form, and it's specifically -- the project is the CSOMP improvements, and the dates of this is, it looks like 5/6 of '15.
Are you able to read the project objectives, the first bullet point under Project Objectives?

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A. "Add pattern and frequency."
Q. Do you know prior to this date whether pattern and frequency were elements of the CSOMP program?
A. The original CSOMP program was threshold based.
Q. So it did not take into account pattern and frequency?
A. Not inherently, no.
Q. Okay. Can you read underneath, it is the next section down, "Impact if project not performed"? You may not be able to read it. It is very, very fuzzy.
Are you able to read that?
A. I'm trying to focus on it.
Q. Let me -- let me see if I can read it and to the extent you think it doesn't reflect the document, let me know.
"Significant regulatory risk. Current program does not meet minimum DEA requirements, especially pattern and frequency."
The next bullet point says: "Civil monetary penalty (McKesson recent fine of 150 million)."

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The next one says: "Suspension or loss of license and ability to sell control products."
And the final bullet point is: "Risk to the company reputation and patients if product is distributed in illegitimate sources."
Do you think that those impacts if this project is not implicated -- not performed are accurate or is that overstating the risks of impact?
MR. PADGETT: Object to form.
Go ahead.
BY THE WITNESS:
A. We have threshold system, we did have other checks on -- on patterns and frequency doing purchase history checks and -- and checks on our -- on our customers. This was an enhancement to the system to make it more automated because it was originally just a threshold system. I think the -- I think the impacts are a little bit overstated.
BY MR. YOUNG:
Q. Let me focus you on one of them.
A. Okay.
Q. The comment, I'm trying to figure out who the author of this is. It may be Tracey Hernandez. She is identified as the owner of this project.

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The comment is: "Current program does not meet minimum DEA requirements, especially pattern and frequency."

Do you agree or disagree with that conclusion?

A. The way our system was designed was on a threshold basis. It did pick up on pattern and frequency, but this was an enhancement to that --

Q. Yeah.

A. -- system.

Q. I understand that. That's not my question.

My question is: Do you agree or disagree with Tracey Hernandez's conclusion that the current program does not meet minimum DEA requirements?

A. I believe they were meet --

MR. PADGETT: Object to form.

Go ahead.

BY THE WITNESS:

A. I believe we were meeting DEA requirements --

BY MR. YOUNG:

Q. So --

A. -- of the order monitoring system.

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Q. So you disagree with Tracey Hernandez's conclusion?

A. I believe that we were complying with regulations.

Q. Do you know whether or not this Project Initiation Form was implemented?

A. It was.

Q. Was it implemented prior to your return to the company?

A. It was in process.

Q. There is another -- it might be better if I see this real quick.

There is another section on here, which is the second bullet point, it says: "Assess by DEA number rather than account number."

Do you know what that's describing?

A. Where does that say that?

Q. Of the second bullet point in the very first box. The first one is: "Add pattern and frequency." The -- the bullet below that. It says: "Assess by DEA number rather than account number."

A. Occasionally we have accounts that -- pharmacy customers that may have different accounts, they may have a retail pharmacy, they may have service

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340B -- or not 340B, I'm on this. I forget the designation for indigent patients.

Q. I think it is 340B.

A. Oh, okay. I'm getting too many acronyms here.

Q. 30(b)(6) is what you were thinking.

A. Sorry. Yeah. That was -- yeah.

So they may have two separate accounts that they order on and the way the -- the CSOMP was originally designed, it was designed on account number. So we changed that to -- to trigger off the DEA number so we could more accurately reflect any -- any issues at a -- at a pharmacy.

Q. Do you know whether it was ever uncovered that a single location pharmacy was using more than one account number to obtain multiple threshold amounts?

A. No.

Q. Did you ever discuss these findings with Tracey Hernandez?

A. She was gone when I came back.

Q. Did you ever review any reports that she may have written or memoranda that she wrote about that particular bullet point, the DEA number rather

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than account number?

A. Not with her. I discussed that with my staff, and we thought that would be a good enhancement to the system as it was.

Q. But it wasn't -- it wasn't part of the system prior to your departure?

A. No.

Q. Okay. The next exhibit is Exhibit 43. Let's see. I think I'm off by one. There we go. Exhibit 43, which is an e-mail from Tracey Hernandez. There you go.

So I'll direct your attention to Page 4 of that exhibit, which is a type of report titled "CSOMP Fixes and Modifications Required," and it is dated February 18th, 2015.

A. Okay.

Q. Have you seen this before?

A. I can't recall this specifically, but I'm -- assume I did.

Q. Okay. So let's just walk through it quickly. It's -- the first bulleted section, the CSOMP Issues - Broken Functionality. And the first section says:

"If a separate controlled drug order comes

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into CSOMP while another is pended for the same family, the system will allow the second order to go through. This order should be pending as well."

Are you familiar with that broken -- broken functionality of CSOMP?

A. I'm not sure what she is talking about here because as -- as --

Q. So --

A. -- the functionality of CSOMP is that if an order was suspended in a drug family, it blocked all subsequent drug families.

Q. So in the middle of that first full paragraph, there is a sentence that begins "System." It says:

"System is currently set that if both items are on the same order, it will pend, but if both items are on separate orders, the order coming through after the first order is placed on CSOMP hold will release without going through CSOMP."

Now, I understand you weren't there at the time, but do you have any reason to believe that isn't the case of the system at the time?

A. Can you give me a second?

Q. Sure.

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A. I'm not certain, but I -- I think I know what the -- the issue was here.

We have -- a few of our divisions do multiple-day deliveries. Most are set up to where they -- you get orders at night, they deliver in the morning. We have some in the metropolitan areas that someone can order in the morning and then order again in the afternoon. That -- that order that comes in that may -- that may pass the CSOMP test and is staged for shipment and then another order comes in that may for -- for later in the day or the next day comes in, that first order will not get held up, it will go -- it will ship.

Q. That's not what this is describing.

A. Okay.

Q. This actually says the system is currently set that if both items are on the same order, it will pend, but if both items are on separate orders, the second order coming through after the first order is placed on hold, it will release?

A. I don't believe that's --

Q. That's the opposite of what you described?

A. I don't believe that's true.

Q. Okay.

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A. That's not the way the system is designed.

Q. Do you know whether this broken functionality Section 1 was ever fixed after February 18th, 2015, in the CSOMP at H.D. Smith?

A. I don't know that it was broken.

Q. Do you --

A. My -- to my knowledge, if -- if an order was -- if an order in the same drug family was -- was placed after an order was put on hold, it would hold that order.

Q. Okay.

A. And all order -- all subsequent orders in that drug family.

Q. Okay. Move on to Section 3. It is talking about rejection code access and it gives a specific -- a question about who has access to release a Z5 CSOMP hold.

Do you know what a Z5 hold is?

A. Let me read through this for a second.

I -- I don't know what Z5 is.

Q. Okay.

A. It is a code in -- in our SAP program.

Q. So this finding on the broken functionality of CSOMP found that 448 people in the

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company could release a Z5 CSOMP hold. And the conclusion was it needs to be limited to an extremely short list of compliance personnel.

You had testified earlier that under your tenure only a small handful of compliance personnel had the ability to increase URLs, right?

Do you know whether that is true for rejection codes like the Z5, because this is concluding otherwise?

A. Yeah, I don't know what the Z5 CSOMP hold is.

Q. Okay. Who would have the most knowledge about what the Z5 CSOMP hold is?

A. Probably somebody in IT that works on the -- on the CSOMP program.

Q. And when you de -- I think you testified earlier that you were the architect, not the data architect, but the architect of CSOMP.

Who in the IT department did you work with to -- to build this system?

A. Originally?

Q. Yes.

A. Rob Kashmer, Don Huckstep, and the other name is escaping me, but there was three people that I

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worked mainly with. They are no longer with -- none of -- none of them are long -- no longer with the company.

Q. Can you identify the person with the most knowledge at H.D. Smith right now that would be able to answer what a Z5 CSOMP hold code is?

A. I can inquire, but I don't know.

Q. Okay. One more thing on this one, which is, I believe -- where is this one?

So this appears to be a -- the document we've been looking at appears to be support for that earlier project improvement form that we were talking about. No. 5 on this says: "Need to enhance CSOMP with tools to detect orders of unusual frequency and/or pattern."

I just want to verify you -- you testified that the CSOMP at the time of this writing did not include frequency or pattern tools, right?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. It did not inherently detect orders of unusual frequency or pattern. It was threshold based.

BY MR. YOUNG:

Q. And Item 6 is the multiple account number

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issue that we discussed before. And in this case the author of this, which I assume is Tracey, said: "Because the URL is assigned by account number, this may cause the customer to double or, in some cases, triple the amount of URL they are permitted. Three account numbers equals three times the URL. This can occur if a customer has a 340B, Smartsource and/or standard account."

Does this refresh your recollection at all about the dangers of using account numbers versus DEA numbers in the CSOMP system?

A. That's one of the enhancements we did to closing the gap that there may be. It's not -- nothing -- to my knowledge, we didn't have any customers that manipulated that part of that where our CSOMP system was based on account numbers.

Q. Okay. That's it for that document.

Hold on. We are going to skip ahead a little bit. 46. Okay.

I'm going to hand you Exhibit 46. Which is a lengthy document. It is the amicus brief of the HDMA in support of Cardinal Health.

Have you seen that amicus brief before?

A. I have.

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Q. When did you -- when did you first see that?

A. I don't know when I originally first saw it. I had reviewed it.

Q. There is a section in that brief on Page 2 which says: "HDMA's members have not only statutory and regulatory responsibilities to detect and prevent diversion of controlled prescription drugs" --

A. Wait. Wait. Where -- where are you --

MR. PADGETT: This, Page 2.

BY MR. YOUNG:

Q. Yeah, Page 2. It should be highlighted on your -- your copy. That "HDMA's members."

A. Okay.

Q. Okay. Can you go ahead and read that paragraph for us? And then I want to ask you about H.D. Smith's opinions about that paragraph.

A. "HDA's" -- "HDMA's members have not only statutory and regulatory responsibilities to detect and protect diversion of controlled prescription drugs, but undertake such efforts as responsible members of society. The public health dangers associated with the diversion and abuse of controlled prescription drugs have been well recognized over the

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years by Congress, DEA, HDMA and its members, and public health authorities."

Q. Okay. Does H.D. Smith acknowledge a statutory and regulatory responsibility to detect and prevent diversion of controlled prescription drugs in order to protect society?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. We have a regulatory responsibility to maintain effective controls against diversion.

BY MR. YOUNG:

Q. That wasn't my question.

The HDMA issued this amicus brief in support of one of its members, Cardinal Health, and I want to know to what extent you agree or disagree with the positions espoused by the HDMA in this brief.

The first sentence says "HDMA members," and so here we are going to say, H.D. Smith has not only a statutory and regulatory responsibility to detect and prevent diversion of controlled prescription drugs, but undertakes such efforts as responsible members of society.

Do you agree or disagree with that statement?

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MR. PADGETT: Object to form.
BY THE WITNESS:
A. Again, in -- in our place in the supply chain, our responsibility and our regulatory responsibility is to maintain effective controls against diversion.
BY MR. YOUNG:
Q. Do you agree or disagree with the next sentence: "The public health dangers associated with diversion and abuse have been well recognized over the years."
A. I agree with that.
Q. Let's see. There is another highlighted section.
Can you turn to Page 3 with the highlighted section that begins, "With the agency," and in this case the agency being the DEA.
Can you read that for us?
A. "The agency has failed to provide meaningful guidance to assist the regulated industry in complying with DEA's interpretation of its implementing regulations. HDMA respectfully submits that, despite the agency's oft-recited refrain that the regulations are 'clear,' the regulated industry

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does not know the rules of the road because DEA has not adequately explained them."
Q. Does H.D. Smith agree or disagree with that statement?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I would agree that DEA has not historically given clear guidance and has given shifting guidance and -- to the regulated industry.
BY MR. YOUNG:
Q. You testified earlier about receiving the two Joe Rannazzisi letters from the DEA, correct?
A. Correct.
Q. And I think you testified actually that those were forms of guidance, right?
A. Yes.
Q. Is there something in the Rannazzisi letters that you received in, is it '08 and '07, that was unclear to H.D. Smith?
MR. PADGETT: 'It was '06 and '07.
BY MR. YOUNG:
Q. '06 and '07. Sorry.
MR. PADGETT: Object to form.
BY THE WITNESS:

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A. What I'm referring to is -- is guidance that -- that we have asked for and not gotten. You know, there are -- there are different, you know, communications I've had with DEA where we have not gotten clear guidance, there has been a shifting interpretation of the order monitoring regulation that's been in place for decades, and, you know, still today we ask for assistance and get limited assistance and guidance from DEA, who regulates us.
BY MR. YOUNG:
Q. Was the directive by the DEA to H.D. Smith to create a suspicious order monitoring program to identify and report suspicious orders, was that clear to H.D. Smith, those obligations to create a -- a SOM program, or was that unclear?
A. Are you talking about the automated system that we put in place?
Q. Yes.
A. That was not a mandate. We voluntarily created that system.
Q. Okay. Were -- were the laws, the Controlled Substances Act and attendant regulations, were those clear or unclear to H.D. Smith at the time that it implemented its CSOMP program?

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A. It was unclear to the way the DEA was interpreting them and what DEA -- and what industry practice was at the time.
Q. Was the requirement to monitor pattern and frequency in a CSOMP program clear or unclear in 2010?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. When we've developed our CSOMP program, it was clear to DEA through numerous communications with DEA that our system was going to be a threshold system to start out with. We never received any guidance for or against that system and -- and it was clearly communicated to DEA as to how our system operated.
BY MR. YOUNG:
Q. That wasn't my question. My question is: In 2010 after the implementation of your CSOMP program, was it clear or unclear to H.D. Smith that pattern and frequency were required elements of a CSOMP program?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I can only answer that that our system, DEA knew what our system was, it was a threshold-based system. To my knowledge many of the order monitoring

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systems that were -- that were created in industry were threshold based and then we were in the midst of developing to enhance that to detect more clearly pattern and frequency.
BY MR. YOUNG:
Q. So H.D. Smith did not view pattern and frequency as required elements of its CSOMP program in 2010?
A. We thought we were compliant with the regulation with the threshold-based system which gave us the ability to monitor our customers' purchases.
Q. Was pattern a required element of the CSOMP program in 2010, the pattern of orders from customers?
MR. PADGETT: I'll object to form.
BY THE WITNESS:
A. I'm not clear what you are asking.
BY MR. YOUNG:
Q. In 2010, after implementation of your CSOMP program, there were instructions, or -- or I should say communications with the DEA.
Is there anything that the DEA shared with H.D. Smith that led H.D. Smith to conclude that it did not have to include pattern or frequency in its CSOMP

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program?
A. There was nothing communicated either way.
Q. On what did H.D. Smith rely in not including pattern and frequency elements in its CSOMP program? What was the basis for that decision?
A. The basis was communication, consistent communication with DEA in the development of our CSOMP program and they knew exactly what our CSOMP program was going to detect.
Q. But you've got no -- nothing in writing from the DEA saying that that was acceptable?
A. They won't put anything in writing.
Q. Again, you don't have anything in writing from the DEA?
A. I don't.
Q. You don't have anything in writing from Congress that says that that was acceptable, right?
A. I don't.
Q. How about the Department of Justice or state board of pharmacies or state attorneys general, have any of them given you anything in writing which says it is acceptable to not include pattern and frequency in your CSOMP program?
A. No.

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Q. Okay. Turning to Page 10 of this brief, there is another highlighted section. Can you read that for us?
A. "The societal costs of prescription drug abuse are huge, and the development and implementation of practices and procedures to detect and prevent diversion are burdens that HDMA members willingly bear."
Q. Do you agree that the societal costs of prescription drug abuse are huge?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Define what the societal costs are. Are we talking monetary or --
BY MR. YOUNG:
Q. HDMA, an organization that H.D. Smith is a member of and serves on committees for and supports, prepared this brief and this brief made this remark. And I'm asking whether or not you an -- you agree or disagree with this remark: "The societal costs of prescription drug abuse are huge"?
A. And I'm trying to get more clarification on what the definition of the societal costs are. I was not there when this was drafted.

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Q. Okay. So do you opine that the societal costs of prescription drug abuse are not huge?
A. I'm just trying to get a better clarification of what the societal costs are. If you mean the societal costs are deaths of overdose, of drug abuse, there is -- you know, statistically there is an increasing number of people that die from prescription drug overdoses and opioid overdoses altogether.
Q. And would you call those societal costs?
A. It would be one of the definitions, yes.
Q. And would you refer to those as huge or not huge?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I -- I do think they are huge. We -- you know, we have a -- you know, we take our responsibility serious.
BY MR. YOUNG:
Q. Okay. I want to turn your attention to -- this is going back to Mallinckrodt for those of you on the phone. This is Exhibit 54 that I will hand you which is a Confidentiality and Restricted Use Agreement.

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Is this the first time you've seen this agreement?
A. I can't be certain.
Q. Okay. And you don't need to read the whole thing. I just really wanted to ask you a couple of -- of questions. And you may not be familiar, you may not know the answers to these, but there is a highlighted portion at the bottom of Page 1 which begins with: "Whereas, Mallinckrodt."
A. Do you want me to read that?
Q. Can you read that, please?
A. "Whereas, Mallinckrodt, through its chargeback system, can identify some of the pharmacy customers who are purchasing its controlled substances from multiple distributors/wholesalers and the volumes of pharmacy customers are purchasing from each distributor/wholesaler."
Q. And I don't need you to -- to dig into great detail about the chargeback system, but can you just explain how it is that Mallinckrodt through the chargeback system is able to identify pharmacy customers purchasing controlled substances from multiple distributors?
MR. MILLER: Objection to form and scope on

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behalf of Mallinckrodt.
MR. PADGETT: Same objection.
BY THE WITNESS:
A. To my knowledge, H.D. Smith shares data with Mallinckrodt on Mallinckrodt products going to their pharmacy customers.
BY MR. YOUNG:
Q. Is that a two-way sharing, does H.D. Smith send information to Mallinckrodt only or does it also receive information from Mallinckrodt?
A. I don't know.
Q. Who at H.D. Smith is in charge of the information sharing with Mallinckrodt?
A. I don't know if we have anybody at H.D. Smith anymore that does that.
Q. Historically, who -- is there one person --
A. We had a -- we had a department that was a chargeback department but they are no longer.
Q. And who was the person that headed up the chargeback department, if you recall?
A. I -- I don't know.
Q. Do you know whether or not any pharmacy customers were identified and you ceased doing

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business with them as a result of this information sharing with Mallinckrodt?
A. We had, like, quarterly discussions with Mallinckrodt about customers, we would conduct due diligence on customers they brought to our attention, additional due diligence. There were also notices that Mallinckrodt would put out on certain customers that they were denying chargebacks to and many times it would not be customers of ours but we would block them in our system to make sure that they did not become customers of ours.
Q. Was Mallinckrodt the only manufacturer or -- or -- or vendor of yours that provided this level of information?
A. We had meetings fairly regular for a time with Purdue Pharma.
Q. Do you know whether or not Purdue Pharma shared information with H.D. Smith that resulted in H.D. Smith discontinuing servicing pharmacies?
A. I can't -- I can't answer that specifically. We did share information about pharmacies. They may have resulted, after we did additional due diligence where we would have discontinued selling controlled, but unless we get

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specific, I wouldn't know that answer.
Q. Those are the only two companies, Mallinckrodt and Purdue, that you recall H.D. Smith having this level of communication with?
A. We've had conversations in the past with other -- other manufacturers where orders of ours may have hit their suspicious order monitoring program, the manufacturers, and they would have called us to discuss that. I remember having discussions with Watson. I can't recall the others.
Q. I want to see if this may help. I'm going to give you Exhibit 55 --
A. Okay.
Q. -- which is a -- I think an e-mail thread. It may be a collection of e-mails other than a thread. I'm not entirely sure.
Have you seen this e-mail before?
A. I'm sure I have. It is something that is addressed to me.
Q. Did -- did H.D. Smith have an agreement with Teva or its predecessor entities or related affiliates regarding sort of exchange of -- of information like we previously discussed?
A. I don't know specifically if we had an

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agreement with Teva. We've had conversations with them. There is a industry group that meets occasionally and I think Teva is on that or attends it, but specifically an agreement, I'm not aware.

Q. What is the name of that industry group? You knew I was going to ask.

A. Oh, boy. It's -- it's a New Jersey industry group. I -- I don't know the name of it.

Q. Okay. If you think of it, let us know through counsel.

So the -- part of this e-mail thread goes from a Marianne at Teva to a Lynne Soja at H.D. Smith.

Who is -- do you know who Lynne is?

A. I believe she is a buyer.

Q. Okay. And the e-mail suggests that Teva has identified three H.D. Smith customers and it's actually refusing to release any oxycodone for H.D. Smith unless they receive the completed forms and analyzed data.

Is that unusual for a manufacturer to take that step?

A. No. It's becoming more and more standard, if -- you know, the -- the manufacturers have order monitoring systems and if they -- if -- if a manu- --

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if a distributor hits their system, they are going to want information before they release an order.

Q. So is H.D. Smith making orders specific to customers -- or for customers to manufacturers, like -- like how did Teva know to hold a particular order that it was for these three customers?

A. Let me read this for a second.

Q. Yeah. And I'm not sure if you understand my question because I don't think it was worded that well.

A. Nah, I just want to read it and then have you --

Q. Okay.

A. -- reask that, so...

Okay. Can you reask that then?

Q. Does H.D. Smith place orders with Teva for specific customers or does it buy in bulk?

A. No. They buy in bulk.

Q. So how did Teva know whether or not a particular oxycodone order to H.D. Smith was going to these three pharmacies?

MR. PADGETT: Object to form.

BY THE WITNESS:

A. I -- I -- I don't know.

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BY MR. YOUNG:

Q. Okay.

A. I don't know if these pharmacies were on Teva's radar. I don't know. They wouldn't -- to my knowledge, they wouldn't have that information unless we specifically shipped an order to a pharmacy and they would have that information.

Q. And you mentioned, I think, that this is becoming more typical recently, right, this --

A. We are seeing that, yes.

Q. Okay. We'll -- we'll -- we'll blow through some questions here pretty quickly, I think.

Did H.D. Smith ever undertake interaction or communication with the FDA relating to the scheduling of drugs? I assume not, but I have to ask.

A. We don't.

Q. How about with regard to the setting of quotas?

A. We don't have anything to do with that.

Q. Production of quotas.

I just had to make sure.

Did H.D. Smith ever sell controlled substances in Cuyahoga County or Cleveland without first having them complete a customer profile form?

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A. Not to my knowledge, but I'd have to check our -- our due diligence files.

Q. Do you recall whether H.D. Smith ever shipped an order into Cuyahoga County or Cleveland which was later reported to the DEA as a suspicious order?

A. No.

Q. Has H.D. Smith conducted any type of retrospective analysis of past orders of controlled substances from Cuyahoga County or Cleveland which identified unreported or undetected suspicious orders?

A. No.

Q. Has H.D. Smith conducted site visits of its pharmacy customers in Cleveland or Cuyahoga County within the last five years?

A. I would have to check our files to know precisely.

Q. Would that be the due diligence files again?

A. Yes.

Q. That's the central?

A. Yes.

Q. Okay. At any point in time has H.D. Smith re -- reviewed, assessed or analyzed the URLs for

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Cleveland or Cuyahoga County pharmacy customers?
A. Yes.
Q. Have you done so within the last 18 months?
A. Again, I'm not certain on the dates.
Q. Online pharmacies, does H.D. Smith still do business with online pharmacies?
A. We don't do business with online pharmacies.
Q. Have you ever done business with online pharmacies?
A. Not knowingly.
Q. I think you mentioned before that was something that the DEA was very focused on?
A. Yes.
Q. In the early 2000s.
Did the DEA help H.D. Smith to identify online pharmacies that it was unknowingly doing business with?
A. I don't think -- not in particular.
Q. How did H.D. Smith identify online pharmacies that it was unknowingly doing business with?
A. There was various ways. I mean, we -- we

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got -- if we had any documentation, I told you that we used to get -- Kyle Wright used to send out an e-mail on pharmacies that had been -- where another wholesaler had -- had stopped doing business with a particular pharmacy and we would make sure that we did not do business with those pharmacies.
We -- you know, we -- just as -- as I answered, we never did any business with an online pharmacy that I am aware of.
Q. Is H.D. Smith aware that prescription opioids dispensed in one city can end up in other cities?
A. That's a --
Q. You can answer. That's a terrible question.
MR. PADGETT: I'll object to form. I join your objection.
BY THE WITNESS:
A. Yes.
BY MR. YOUNG:
Q. Let me ask it a different way.
Are you familiar with the phrase "the oxy express"?
A. Yes.

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Q. What does that mean?
A. In my mind it refers to prescriptions in, for example, in Florida, in South Florida that may have been -- people from other areas of the country would visit pain clinics in Florida, get prescriptions, get them filled and go back.
Q. Did H.D. Smith ever conduct any investigations about South Florida pharmacies that revealed what you just described, people from out of state coming down to South Florida to buy these pills?
A. Nothing definitive. You know, even if we had dispensing information and a -- a pharmacy in South Florida was dispensing a prescription for someone that we -- we identified coming from 100 miles away, we don't know if that's in Florida or not. You know, we have done surveillance at pharmacies, I have done surveillance at pain clinics, I've seen out-of-state plates.
Again, we don't conduct criminal investigations, so I will -- to be definitive, I can't give you an answer. My assumption would be that there was -- that was going on.
Q. Do you recall whether any of the license plates that you observed in Florida pharmacies were

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from Ohio?
A. They could have been.
Q. But you don't recall specifically?
A. Not specifically.
Q. Would there be evidence in the due diligence files of the South Florida pharmacies that you investigated that indicated the state of origin of the license plate?
A. If it would have been specifically identified by the investigator.
Q. Okay. Just two more, two more items.
We are skipping to Exhibit 57, which you may not have seen before. This is an amendment to an agreement between H.D. Smith and Actavis. Take a look at that and let me know when you are ready to talk.
MR. PADGETT: Take your time.
BY THE WITNESS:
A. I have never seen it before.
BY MR. YOUNG:
Q. Have -- are you familiar with a agreement between a manufacturer and H.D. Smith that involves profit sharing? Have you ever heard that phrase used with regard to manufacturer/distributor agreements?
A. Not that I know.

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MR. PADGETT: I'll object -- I'll -- I'll object to scope.
BY MR. YOUNG:
Q. Let me direct your attention in this agreement to -- where is that profit sharing?
MR. PADGETT: While you are looking, continuing objection to this exhibit and questions on it on the basis of scope.
BY MR. YOUNG:
Q. Who would be the person at H.D. Smith with the most knowledge about agreements between manufacturers and H.D. Smith, purchase agreements?
A. Probably the person on this e-mail, Dena Mando.
Q. Is she still with H.D. Smith?
A. I don't know if she is with H.D. -- I -- I don't know.
Q. From a compliance perspective, do you identify any issue with manufacturers sharing profits with distributors?
MR. PADGETT: Same objection.
BY THE WITNESS:
A. I'd have to know more about the agreement and more about what the agreement is and what -- what

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it pertains to to give you a definitive answer on that.
BY MR. YOUNG:
Q. Is -- is that type of agreement review part of your job duties, does -- does compliance get involved with reviewing agreements with manufacturers?
A. We do not.
Q. Who would be the department within H.D. Smith that would? Is that regulatory, legal?
A. I -- I don't know if we have anybody left.
Q. Okay. Let me just take a look at this one.
Let me -- let me hand you Exhibit 58, which is an e-mail to you from Lynda Eleazer. I might not be saying that right.
Do you recall -- I know this is a while ago. Do you recall receiving this e-mail?
A. I'm sure I did and that name is familiar to me.
Q. This e-mail seems to be a -- a request by the DEA diversion investigator to provide a purchase history summary of controlled substances by a particular facility called Budget Drug & Wellness Center.

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Do you recall that particular pharmacy customer or -- or customer, I should say?
A. Can you give me a second?
Q. Sure.
A. I don't necessarily remember this specific customer.
Q. If Budget Drug & Wellness had both DEA numbers immediately suspended on September 12th, 2005, and was not authorized to purchase or dispense controlleds from September 12th, '05 to April 13th, '06, is it fair to say that H.D. Smith would not have shipped Budget Drug & Wellness any controlled substances?
MR. PADGETT: I'll object to form.
BY THE WITNESS:
A. I'd -- I would have to see what was shipped to this customer, whether there was anything at all. I don't know during this time period.
BY MR. YOUNG:
Q. Okay. But if you knew that the DEA number was suspended, H.D. Smith has policies and procedures in place that would cause the cessation of shipping to someone without a DEA number, right?
A. Yes.

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Q. And so if you were aware that this particular pharmacy had its numbers suspended and you continued to ship to them, that would be a violation of the CSA, right?
A. If we knew that.
Q. So yes?
A. If -- if we knew that they were suspended and continued to ship.
Q. Right.
So in that scenario, that would be a violation of the Controlled Substances Act?
A. If we knew that the registration was suspended and we continued to ship.
Q. Okay. Okay. I want to direct your attention, final exhibit, final line of questions, get excited everybody, this is regarding the Master Pharmaceutical case or Masters Pharmaceutical case which is a late entry, handwritten, No. 60 for you keeping track.
Are you familiar with the Masters case?
A. I am.
Q. How are you familiar, how did you come to know about the Masters case?
Do you recall the first instance?

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A. It -- it -- it -- I don't recall the first instance. It was -- it went on for a while. I've read this, I've read the 300-page part of it, so...
Q. In preparation for today's deposition, did you specifically go back and read the Masters opinion?
A. I did.
Q. Oh, you did, okay.
Does -- well, let's -- let's start on Page 4 of the opinion. There should be a highlighted --
MR. YOUNG: You don't have it? Oh, you don't have yours. Oh.
MR. PADGETT: I can look off of with him.
MR. YOUNG: Okay.
MR. PADGETT: Do you want it on for the Elmo?
MR. YOUNG: The Elmo, yeah.
BY MR. YOUNG:
Q. Sorry. Page 4, last paragraph, it should be highlighted.
Can you read that for us?
A. "The 'security requirement' at the heart of this case mandates that distributors 'design and operate a system' to identify 'suspicious orders of controlled substances' and report those orders to DEA

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(the Reporting Requirement). 21 CFR 1301.74(b). The Reporting Requirement is a relatively modest one. It requires only that a distributor provide basic information about certain orders to DEA, so that DEA investigators in the field can aggregate reports from every point along the legally-regulated supply chain and use the information to ferret out potential illegal activity. Southwood" --
Q. You can skip that.
A. Okay.
"Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct 'due diligence' and if it is able to determine that the order is not likely to be diverted into illegal channels, ship the order (the Shipping Requirement)."
Q. So does H.D. Smith acknowledge that that provision that you just read is the reporting requirement under federal regulations?
MR. PADGETT: I'll object to form.
BY THE WITNESS:
A. The regulation states that we have to report suspicious order when we discover.
BY MR. YOUNG:

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Q. So the provision that you just read, do you agree or disagree that that is the reporting requirement under federal regulations?
A. "Design and operate a system and identify suspicious orders of controlled substance," I agree with that.
Q. It -- does it also include the shipping requirement under federal regulations?
A. There is not a shipping requirement.
MR. PADGETT: Object to form.
BY MR. YOUNG:
Q. Okay. So the -- the parenthetical at the end of the paragraph you just read says "the shipping requirement."
Is it your testimony here today that there is no such shipping requirement?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. My understanding is in federal regulation there is no shipping requirement.
BY MR. YOUNG:
Q. Okay. So the second half of the provision that you just read, which the court has labeled "the shipping requirement," H.D. Smith disagrees with?

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A. It has been our -- you know, our practice that when we discover a suspicious order and we identify a suspicious order and we report that order to DEA, we do not ship that.
Q. Yeah. That's not my question.
My question is whether or not H.D. Smith disagrees with the court's encapsulation of what it calls "the shipping requirement" under federal regulations?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. To my knowledge in the federal regulations there is no shipping requirement.
BY MR. YOUNG:
Q. Okay. And what is the basis for the conclusion that there is no shipping requirement? Is it your individual interpretation or has H.D. Smith reached a formal position or opinion on whether or not the shipping requirement exists or doesn't exist?
A. It -- there is nothing in the federal regulation that -- that specifies anything about a shipping requirement.
Q. If H.D. Smith fails to follow the reporting requirement, is that a violation of the law?

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A. If we fail to follow --
Q. Report -- the reporting requirement?
A. Suspicious order when we identify it?
Q. Um-hum.
A. It would be in violation of the regulation.
Q. And if H.D. Smith reports a suspicious order and ships it, is that a violation of the federal requirements, federal regulations?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Again, what time period are we talking?
BY MR. YOUNG:
Q. At any time period.
A. Well, as we discussed, before our order monitoring program went into place, there were orders that were shipped and reported as suspicious after the fact as per the -- the industry standard and according to what we -- we were under the assumption that DEA, that was their interpretation and what we should be doing. Once we had our order monitoring system in place, we did not ship any orders that we identified as suspicious.
BY MR. YOUNG:

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Q. So the provision of the Masters case, which you disagree with, essentially says what you just described, but you disagree with it and I want to just make sure because this is an important aspect of this case. It's important for the court and the jury to understand whether or not H.D. Smith recognizes and agrees with the Masters opinion on a shipping requirement or disagrees with it. So you have to indulge me while we revisit this one more time.
What the -- what the opinion says is once a distributor has reported a suspicious order, so the suspicious order has been reported, it must make one of two choices, decline to ship the order or conduct some due diligence and if it is able to determine that the order is not likely to be diverted into illegal channels, ship the order.
Do you agree or disagree that that is the law under federal regulations?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. As a practice, if we report a suspicious order, we do not ship it. As far as a -- a shipping requirement in the federal regulations, there isn't one.

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BY MR. YOUNG:
Q. Sir, again, that is not my question. My question is whether you agree or disagree with the statement I just made, that once an order has been reported as suspicious, you must make one of two choices, decline to ship or conduct due diligence and eventually ship?
A. And we decline to ship.
MR. PADGETT: Objection to form; asked and answered.
BY MR. YOUNG:
Q. I'm sorry?
A. And we decline to ship.
Q. Has there ever been an occasion in which H.D. Smith has reported a suspicious order yet shipped the suspicious order?
MR. PADGETT: Objection; asked and answered.
BY THE WITNESS:
A. What time period?
BY MR. YOUNG:
Q. At any time.
A. As we discussed earlier, before our automated system it was an after-the-fact review by the operations manager and we reported orders as

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suspicious and they had already been shipped.
Q. So your testimony is that H.D. Smith has never identified a suspicious order and shipped a suspicious order?
A. If we identified a suspicious order, we did not ship it.
Q. So any occasion in which we found a suspicious order or an order that met the definition of suspicious and H.D. Smith shipped it, that would be a violation of the CSA?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Who is making the definition -- who is making the determination of whether it is suspicious?
BY MR. YOUNG:
Q. Any occasion in which an order meets the criteria identified by the regulations as a suspicious order and was shipped by H.D. Smith, that would be a violation of the CSA?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. Our -- our system was designed to -- to identify potential orders that may be suspicious. Because they hit our system did not make them

suspicious. It was after we determined whether they were suspicious or not.
BY MR. YOUNG:
Q. Is the determination of whether an order is suspicious or not solely within the purview of the distributor or is it an objective evaluation?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. There is no definitive definition of what constitutes a suspicious order.
BY MR. YOUNG:
Q. And one final question. For the time period that H.D. Smith's CSOMP program did not include pattern or frequency, so it was only a threshold basis, if there were orders that deviated substantially on pattern or frequency and yet were shipped, would that be a violation of the CSA?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. To my knowledge we never shipped an order that we identified as suspicious during the CSOMP program.
BY MR. YOUNG:
Q. That wasn't my question.

The CSOMP program did not have pattern and frequency, at least until 2015, as elements of it. So did H.D. Smith ship orders that deviated substantially under the regulations, under the CSA on pattern and frequency, not -- not threshold, on pattern and frequency, did it ship those orders?
MR. PADGETT: Object to form.
BY THE WITNESS:
A. I can't answer that definitively and/or if they would have been identified as suspicious or not.
MR. YOUNG: Okay. No further questions.
MR. PADGETT: No questions here.
MR. YOUNG: All right. Prepare for Day 2.
THE VIDEOGRAPHER: We are off the record at 5:42 p.m.
(Time Noted: 5:42 p.m.)
FURTHER DEPONENT SAITH NOT.

REPORTER'S CERTIFICATE

I, JULIANA F. ZAJICEK, C.S.R. No. 84-2604, a Certified Shorthand Reporter, do hereby certify:
That previous to the commencement of the examination of the witness herein, the witness was duly sworn to testify the whole truth concerning the matters herein;
That the foregoing deposition transcript was reported stenographically by me, was thereafter reduced to typewriting under my personal direction and constitutes a true record of the testimony given and the proceedings had;
That the said deposition was taken before me at the time and place specified;
That I am not a relative or employee or attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action.
IN WITNESS WHEREOF, I do hereunto set my hand on this 29th day of November, 2018.

JULIANA F. ZAJICEK, Certified Reporter

DEPOSITION ERRATA SHEET

Assignment No. 200754
Case Caption: In Re: Opiate Litigation

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

GEORGE EUSON

SUBSCRIBED AND SWORN TO
before me this day
of , A.D. 20__.

Notary Public

DEPOSITION ERRATA SHEET

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